



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

Selection Criteria:

Product Name: .;HARVONI
Product Active Ingredient: .
Active Ingredient: .
Active Moiety: .
FDA Received Date: From: 10-OCT-2014 To: 15-MAR-2015
MedDRA® Version* : 17.1
Total Cases** : 759
Number of Pages: 216

Disclaimer: Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

*. "MedDRA® Version" refers to the name and version of the dictionary in use at the time the cases were retrieved from the FDA Adverse Event Reporting System (FAERS). MedDRA Medical Dictionary for Regulatory Activities (MedDRA®) is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to code adverse events, medication errors and other information associated with the use of medical products. A MedDRA® Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is updated twice a year.

**."Total Cases" reflects the number of individual patient case reports associated with the product of interest that were submitted to FDA within the specified time period. A case consists of an initial report and any follow-up reports submitted to FDA. Because FDA may receive reports on the same patient from more than one source, some of these cases may be duplicate patient reports.



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

The information in this report is generated from the FDA Adverse Event Reporting System (FAERS) by using a report query where suspect product(s) or active ingredients are selected from a standardized dictionary and a date range is specified as search criteria. The table below provides the definitions for field headings that are listed on the report.

FAERS data have limitations, including the following. There is no certainty that the reported event was actually due to the product. Reports are often incomplete - a blank field means that no data were provided. FDA does not receive reports on all adverse events that occur with a product. Many factors can influence whether or not an event will be reported, therefore, FAERS data cannot be used to compare products or calculate how frequently an event occurs in the U.S. population.

Field Heading	Definition
FDA Received Date	The date that FDA received the most recent information regarding a case, either as an initial report or follow-up report. The FDA Received Date may not be the same as the date that the event occurred. The event may have occurred days or even months (or years) before the report was sent to (and received by) FDA. Note the displayed date on the report may be later than the query date range if FDA received follow-up information for a case. FDA provides the most current case information available.
Case #	A unique number assigned by FDA that identifies a FAERS case. A case includes the information received in the initial report plus any additional information received in follow-up reports.
Case Type	There are three case types in FAERS: Expedited (15-Day): submitted to FDA by manufacturers; these are reports containing serious, unexpected adverse events Nonexpedited: submitted periodically to FDA by manufacturers; these are reports containing adverse events other than those qualifying for expedited (15-day) reporting Direct: submitted "directly" to FDA by healthcare professionals, patients and other consumers
Health Professional	Indicates whether the initial source who provided information about the event is a health professional (HP). Possible values are; Y - Yes, N - No or the field is blank if it was not reported
Outcomes	Based on FDA regulations, the reported outcome(s) determines whether a case is serious. The outcome categories include congenital anomaly/birth defect (CA), death (DE), disability (DS), hospitalization (HO), life-threatening (LT), other serious important medical event (OT), and required intervention to prevent permanent impairment/damage (RI). A case can have more than one outcome.
Manufacturer Control #	The Manufacturer Control Number is the manufacturer's unique identifier associated with the case. Also referred to as the Company Report Number.
Age	The patient's age, with age unit, based on information provided in the report.
Sex	Patient sex (Male, Female, Unknown).
Country	The country where the event occurred. If not reported, then the country of the reporter. The International Organization for Standardization (ISO) 3166-1 alpha-3 country code is used as an abbreviation for the country.



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Freedom of Information Act (FOIA)
Detailed Report**

Field Heading	Definition
Preferred Term	A Medical Dictionary for Regulatory Activities (MedDRA®) Preferred Term (PT) is used to standardize a “medical concept” in a report. For example, a report of “heart attack” or “myocardial infarct” are standardized to the same Preferred Term, “Myocardial Infarction”. MedDRA is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to “code” adverse events, medication errors and other information associated with the use of medical products
Product	Name of a drug or therapeutic biologic in the case report. A product name can appear as either a brand name (trade name) or an active ingredient name, depending on what was reported.
Role	There are two roles for products listed on the cases. Suspect (S) identifies the product(s) that the initial reporter deemed most likely to be associated with the event. Concomitant (C) identifies products taken at the same time as the suspect product, but not deemed by the initial reporter as being associated with the event.
Route	Reported route of product administration (e.g., oral, topical, injection, sublingual, inhalation).
Dosage Text	Refers to the amount of the product that was taken or given to a patient, and the frequency of administration. For example, 20 mg twice daily.
Duration	The length of time the product was used. For example, if someone reported taking Drug A from January 1 to January 30, the duration would be 30 days.
Manufacturer	The manufacturer of the product, as indicated in the report.



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Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2014	10555873	EXPEDITED (15-DAY)		OT	US- GILEAD-2014-0120484	70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Swelling face	HARVONI	S	UNKNOWN	UNK		GILEAD
	VIBRANCE GREEN	C				
	PLANT FUSION WITH PROTEIN POWDER	C				
	MORINGA	C				
	SEA VEG	C				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2014	10564309	EXPEDITED (15-DAY)			US- GILEAD-2014-0120470	60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Dyspepsia	HARVONI	S	UNKNOWN	UNK		GILEAD

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2014	10567735	DIRECT	Y			49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Diarrhoea	HARVONI	S	ORAL	by mouth		GILEAD

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2014	10569133	EXPEDITED (15-DAY)			US- GILEAD-2014-0121190		Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Gastrointestinal motility disorder	HARVONI	S	UNKNOWN			GILEAD



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

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10-Nov-2014	10574244	EXPEDITED (15-DAY)			US- GILEAD-2014-0121768	61 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Erythema Pruritus		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2014	10574606	EXPEDITED (15-DAY)			US- GILEAD-2014-0122062	51 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Abdominal discomfort Diarrhoea Nausea		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2014	10577680	EXPEDITED (15-DAY)			US- GILEAD-2014-0122164		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI TRUVADA TIVICAY		S UNKNOWN C C			GILEAD GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2014	10580238	EXPEDITED (15-DAY)			US- GILEAD-2014-0122382		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Lymphadenopathy Blister Lymphadenopathy		HARVONI		S UNKNOWN			GILEAD	



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Freedom of Information Act (FOIA)**

Detailed Report

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13-Nov-2014	10582222	EXPEDITED (15-DAY)			US- GILEAD-2014-0121897		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nasopharyngitis Abdominal discomfort Poor quality sleep		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2014	10582315	EXPEDITED (15-DAY)			US- GILEAD-2014-0122431		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dyspepsia		HARVONI ADCIRCA SPIRONOLACTONE		S UNKNOWN C C			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2014	10582504	EXPEDITED (15-DAY)		OT	US- GILEAD-2014-0122112	67 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Renal failure acute Presyncope Dehydration Diarrhoea Dysphagia Sensation of foreign body Chest pain Vomiting		HARVONI PLAVIX COLCHICINE ULORIC METOPROLOL LIPITOR ASPIRIN ESOMEPRAZOLE		S UNKNOWN C C C C C C C	UNK UNK, BID 81 mg, UNK		GILEAD	



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Freedom of Information Act (FOIA)
Detailed Report

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14-Nov-2014	10584733	EXPEDITED (15-DAY)			US- GILEAD-2014-0122459		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Off label use		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2014	10585030	EXPEDITED (15-DAY)			US- GILEAD-2014-0122564		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Protein urine present Urine protein/creatinine ratio increased		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2014	10585940	EXPEDITED (15-DAY)			US- GILEAD-2014-0122925		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hot flush		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2014	10587619	EXPEDITED (15-DAY)			US- GILEAD-2014-0122993		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Gastrointestinal sounds abnormal Diarrhoea Fatigue Headache		HARVONI		S UNKNOWN			GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2014	10588065	EXPEDITED (15-DAY)			US- GILEAD-2014-0122913		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Vitreous floaters		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2014	10588079	EXPEDITED (15-DAY)			US- GILEAD-2014-0122982		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Vomiting Abdominal pain Influenza like illness		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2014	10591545	EXPEDITED (15-DAY)			US- GILEAD-2014-0123020		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Diarrhoea Abdominal discomfort		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2014	10595171	DIRECT	Y			61 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Depression Back pain Feeling abnormal Pain		HARVONI		S ORAL			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

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20-Nov-2014	10596714	EXPEDITED (15-DAY)			US-GILEAD-2014-0123522	67 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nail infection		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2014	10596782	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2014-0123538	58 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Cardiac failure congestive		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2014	10599901	EXPEDITED (15-DAY)			US-GILEAD-2014-0123398		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug dose omission		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2014	10599930	EXPEDITED (15-DAY)			US-GILEAD-2014-0123613		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Gastric disorder		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2014	10599932	EXPEDITED (15-DAY)			US-GILEAD-2014-0123668		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Ear infection		HARVONI		S UNKNOWN			GILEAD	



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Freedom of Information Act (FOIA)

Detailed Report

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21-Nov-2014	10599933	EXPEDITED (15-DAY)			US- GILEAD-2014-0123685	69 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S UNKNOWN			GILEAD	
Diarrhoea		METFORMIN		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2014	10603181	EXPEDITED (15-DAY)			US- GILEAD-2014-0123622		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Palpitations		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2014	10603283	EXPEDITED (15-DAY)			US- GILEAD-2014-0123630	68 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Muscle spasms		HARVONI		S UNKNOWN	UNK		GILEAD	
Diarrhoea								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2014	10603286	EXPEDITED (15-DAY)			US- GILEAD-2014-0123837		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Overdose		HARVONI		S UNKNOWN	2 DF, QD		GILEAD	
		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	



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Freedom of Information Act (FOIA)

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2014	10603290	EXPEDITED (15-DAY)		OT	US- GILEAD-2014-0123734		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Suicidal ideation		HARVONI		S UNKNOWN			GILEAD	
Diarrhoea								
Insomnia								
Migraine								
Pain								
Phantom pain								
Retching								
Unevaluable event								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2014	10606830	DIRECT				59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL			GILEAD	
Diarrhoea								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2014	10615690	DIRECT	Y	HO		51 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Diarrhoea		HARVONI		S	ORAL	1 QD Oral		GILEAD
		METFORMIN		C				
		OMPERAZOLE		C				
		GLYBURIDE		C				
		DICYCLOMINE		C				
		LYRICA		C				
		BUPRENORPHINE		C				
		VITAMIN B1		C				
		AMLODIPINE		C				
Vomiting								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2014	10611592	EXPEDITED (15-DAY)			US- GILEAD-2014-0124327		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Diarrhoea		HARVONI		S	UNKNOWN	UNK		GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Dec-2014	10617853	EXPEDITED (15-DAY)			US- GILEAD-2014-0124412		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Insomnia		HARVONI		S	UNKNOWN	UNK		GILEAD



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2014	10620623	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2014-0124551	50 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pancreatitis Chest pain Paraesthesia oral		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2014	10620628	EXPEDITED (15-DAY)			US- GILEAD-2014-0124462		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Joint swelling Fatigue		HARVONI ATENOLOL AMBIEN D3 MULTIVITAMINS ALA		S UNKNOWN C C C C /00213801/ C	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2014	10622428	DIRECT	Y				Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Vaginal odour Vaginal discharge Vaginal infection		HARVONI		S ORAL			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2014	10622456	DIRECT	Y			80 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Visual impairment Blood pressure increased Hearing impaired		HARVONI		S ORAL	1 tablet		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2014	10622475	DIRECT	Y			57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Depression Fatigue		HARVONI		S ORAL	1 TABLET DAILY PO		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2014	10588049	EXPEDITED (15-DAY)			US- GILEAD-2014-0122699		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Bone pain Abdominal discomfort Diarrhoea Headache Pain Vision blurred		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2014	10623275	EXPEDITED (15-DAY)			US- GILEAD-2014-0124798	61 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2014	10623279	EXPEDITED (15-DAY)			US- GILEAD-2014-0124725		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pruritus generalised Fatigue		HARVONI		S UNKNOWN	UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2014	10623292	EXPEDITED (15-DAY)		OT	US-GILEAD-2014-0125129	59 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Pancytopenia		HARVONI		S UNKNOWN	UNK			GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2014	10623359	EXPEDITED (15-DAY)			US-GILEAD-2014-0124754	75 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug dose omission		HARVONI		S UNKNOWN				GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2014	10636192	DIRECT	Y			62 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Abnormal dreams Somnolence		HARVONI		S ORAL				GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2014	10627291	EXPEDITED (15-DAY)			US-GILEAD-2014-0125103		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Balance disorder Feeling abnormal		HARVONI		S UNKNOWN	UNK			GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2014	10636131	EXPEDITED (15-DAY)			US-GILEAD-2014-0125282		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Blood creatinine increased Glomerular filtration rate decreased		HARVONI		S UNKNOWN	UNK			GILEAD



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2014	10636133	EXPEDITED (15-DAY)			US- GILEAD-2014-0125275		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Increased appetite Feeling cold Hypoglycaemia		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2014	10636146	EXPEDITED (15-DAY)		HO	US- GILEAD-2014-0125102		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chest pain Dyspnoea Headache Weight decreased		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2014	10636150	EXPEDITED (15-DAY)			US- GILEAD-2014-0125482		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2014	10636151	EXPEDITED (15-DAY)			US- GILEAD-2014-0125488	60 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2014	10636153	EXPEDITED (15-DAY)		OT	US- GILEAD-2014-0125677		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Lung infection Sputum discoloured		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2014	10641134	DIRECT	Y			58 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chest pain		HARVONI		S ORAL	HARVONI 90-400 MG DAILY PO		GILEAD	
Abdominal distension Chest discomfort Decreased appetite Dyspnoea Psychomotor hyperactivity								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2014	10641994	EXPEDITED (15-DAY)			US- GILEAD-2014-0125400		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2014	10641995	EXPEDITED (15-DAY)			US- GILEAD-2014-0125483		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue Drug dose omission		HARVONI		S UNKNOWN	UNK		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2014	10641997	EXPEDITED (15-DAY)			US- GILEAD-2014-0125493	62 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nasopharyngitis		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2014	10641998	EXPEDITED (15-DAY)			US- GILEAD-2014-0125902		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dyspepsia Diarrhoea Headache		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2014	10643191	DIRECT	Y			80 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Alopecia		HARVONI		S ORAL			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2014	10643497	EXPEDITED (15-DAY)		OT	DE- GILEAD-2014-0124918		Female	DEU
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Angioedema		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2014	10644615	EXPEDITED (15-DAY)			US- GILEAD-2014-0125989		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Viral infection		HARVONI		S UNKNOWN			GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2014	10644991	DIRECT	Y			51 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Neuropathy peripheral Disease recurrence Fibrosis		HARVONI		S ORAL	1, daily, po		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2014	10646827	EXPEDITED (15-DAY)			US- GILEAD-2014-0126179	82 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hot flush Rash		HARVONI		S UNKNOWN	UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2014	10646857	EXPEDITED (15-DAY)		OT	US- GILEAD-2014-0126042		Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Ascites	HARVONI	S	ORAL	UNK, QD		GILEAD
Back pain	LACTULOSE	C				
Asthenopia						
Blood glucose decreased						
Blood pressure fluctuation						
Dysarthria						
Fatigue						
Feeling abnormal						
Headache						
Hunger						
Hypoglycaemia						
Insomnia						
Joint stiffness						
Muscle spasms						
Peripheral swelling						
Speech disorder						
Yellow skin						

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2014	10646866	EXPEDITED (15-DAY)			US- GILEAD-2014-0126189		Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Chills	HARVONI	S	UNKNOWN			GILEAD
Pyrexia						



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Dec-2014	10646891	EXPEDITED (15-DAY)			US- GILEAD-2014-0126255	58 YR	Male	USA	
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>		<u>Dosage Text</u>		<u>Duration</u>	<u>Manufacturer</u>
Insomnia Headache		HARVONI		S UNKNOWN					GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Dec-2014	10647564	EXPEDITED (15-DAY)		OT	US- GILEAD-2014-0126408		Female	USA	
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>		<u>Dosage Text</u>		<u>Duration</u>	<u>Manufacturer</u>
Hepatic failure Abdominal pain Abdominal rigidity Bladder pain Chest pain Congenital cystic kidney disease Diarrhoea Fatigue Headache Paraesthesia Peripheral swelling Platelet count abnormal Splénomegaly Vasodilatation		HARVONI		S UNKNOWN		UNK			GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
11-Dec-2014	10647597	EXPEDITED (15-DAY)			US- GILEAD-2014-0126199	59 YR	Female	USA	
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>		<u>Dosage Text</u>		<u>Duration</u>	<u>Manufacturer</u>
Influenza like illness Vomiting		HARVONI		S UNKNOWN		UNK			GILEAD



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2014	10651558	DIRECT					Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hypersensitivity Eye discharge Eye pruritus		HARVONI		S ORAL			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2014	10653039	EXPEDITED (15-DAY)			US- GILEAD-2014-0126301		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Myalgia Back pain Fatigue		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2014	10653196	EXPEDITED (15-DAY)			US- GILEAD-2014-0126500		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Off label use		HARVONI PRILOSEC 00661201/		S UNKNOWN C UNKNOWN	UNK UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2014	10653198	EXPEDITED (15-DAY)			US- GILEAD-2014-0126272	49 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Mood swings Anxiety Insomnia		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2014	10653245	EXPEDITED (15-DAY)		OT	US- GILEAD-2014-0127263		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Cognitive disorder		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2014	10653267	EXPEDITED (15-DAY)			US- GILEAD-2014-0126176	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2014	10653296	EXPEDITED (15-DAY)		OT	US- GILEAD-2014-0127261		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Cognitive disorder		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2014	10599334	EXPEDITED (15-DAY)			US- GILEAD-2014-0123390		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Gastroesophageal reflux disease		HARVONI		S ORAL	1 DF, QD		GILEAD	
Headache		PROTONIX		C	40 mg, QD			
		AMBIEN		C	10 mg, QHS			
		VALIUM		C	15 mg, QHS			
		CLONIDINE		C	0.2 mg, BID			
		ZOLOFT		C	50 mg, QD			
		METOPROLOL TARTRATE		C	50 mg, BID			
		OXYCONTIN		C	40 mg, BID			
		OXYCODONE		C	30 mg, Q4Hr			



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2014	10656489	EXPEDITED (15-DAY)			US-GILEAD-2014-0127197		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2014	10656518	EXPEDITED (15-DAY)			US-GILEAD-2014-0127255		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2014	10656524	EXPEDITED (15-DAY)			US-GILEAD-2014-0127391		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Migraine Vomiting		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2014	10656563	EXPEDITED (15-DAY)		OT	US-GILEAD-2014-0127353	44 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sepsis		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2014	10658854	DIRECT		HO			Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Alopecia		HARVONI E PIVIR HBV HARVONI		S C C				



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2014	10659156	DIRECT		OT		63 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dizziness postural Headache		HARVONI		S ORAL			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2014	10659483	EXPEDITED (15-DAY)			US- GILEAD-2014-0127233		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2014	10659536	EXPEDITED (15-DAY)			US- GILEAD-2014-0127495	59 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blister Rash Rash pustular		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2014	10660550	EXPEDITED (15-DAY)			US- GILEAD-2014-0127561	63 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Urinary tract infection		HARVONI		S UNKNOWN	UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2014	10660611	EXPEDITED (15-DAY)			US- GILEAD-2014-0127708		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Neuropathy peripheral Pruritus Rash		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2014	10661419	DIRECT	Y			62 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hallucination, visual		HARVONI		S ORAL	1 tablet, QD, Oral		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2014	10661488	DIRECT	Y			63 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI APAP IMITREX		S ORAL C C	one tablet, QD, Oral			
No therapeutic response								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2014	10599907	EXPEDITED (15-DAY)			US- GILEAD-2014-0123542	63 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Arthralgia		HARVONI ATENOLOL CHLORTHALIDONE		S UNKNOWN C ORAL	UNK 1 DF, UNK		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2014	10662829	EXPEDITED (15-DAY)			US- GILEAD-2014-0126318	62 YR	Unknown	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Urticaria Rash		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2014	10663302	EXPEDITED (15-DAY)			US- GILEAD-2014-0127797	62 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Bronchitis Influenza		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2014	10663305	EXPEDITED (15-DAY)			US- GILEAD-2014-0127887		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Abdominal pain lower		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2014	10663307	EXPEDITED (15-DAY)			US- GILEAD-2014-0128091	62 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2014	10666221	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2014-0127533	65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Clostridium difficile colitis	HARVONI	S	UNKNOWN	UNK		GILEAD
	LISINOPRIL	C	UNKNOWN	20 mg, QD		
	TOPROL	C	UNKNOWN	100 mg, QD		
	NEURONTIN	C	UNKNOWN	300 mg, BID		
	TRIAMTERENE AND HYDROCHLOROTHIAZID	C	UNKNOWN	1 DF, QD		
	LANTUS	C		30 units, QD		
	LIPITOR	C	ORAL	10 mg, QHS		
	PRILOSEC 00661201/	C	UNKNOWN	UNK, QD		
	RESTASIS	C	UNKNOWN	gtts, QD		
	OSCAL D 07451701/	C	UNKNOWN	UNK		
	ASA	C	UNKNOWN	81 mg, QD		
	GABAPENTIN	C				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2014	10667241	DIRECT		OT		60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Chest pain	HARVONI	S	ORAL	1 tablet daily by mouth		GILEAD
Dyspnoea						
Pain						



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2014	10668065	DIRECT		OT		57 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood glucose increased		HARVONI METFORMIN LISINOPRIL		S ORAL C C	1 tab		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2014	10603282	EXPEDITED (15-DAY)			US- GILEAD-2014-0123620	57 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Abnormal dreams Headache Insomnia		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2014	10620625	EXPEDITED (15-DAY)			US- GILEAD-2014-0124433	52 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2014	10642000	EXPEDITED (15-DAY)			US- GILEAD-2014-0125829	58 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Drug dose omission		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2014	10669941	EXPEDITED (15-DAY)			US- GILEAD-2014-0128010		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Eye pain		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2014	10669951	EXPEDITED (15-DAY)			US- GILEAD-2014-0127984		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pollakiuria		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2014	10671699	EXPEDITED (15-DAY)			US- GILEAD-2014-0128412		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue Dyspnoea Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2014	10671720	EXPEDITED (15-DAY)			US- GILEAD-2014-0128449		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Loss of libido Fatigue		HARVONI		S UNKNOWN	UNK		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2014	10673094	EXPEDITED (15-DAY)			US- GILEAD-2014-0128282	50 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2014	10679010	DIRECT	Y	HO		70 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Abdominal distension		HARVONI		S ORAL	1 tablet once daily by mouth		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2014	10682900	DIRECT				59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Influenza Chills Cough Headache Pyrexia		HARVONI		S ORAL	One Tablet			



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2014	10682921	DIRECT	Y	OT		68 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 Tablet		GILEAD	
Chest pain		CERTIRIZINE		C				
		DILTIAZEM		C				
		DORZOLAMIDE		C				
		FINASTERIDE		C				
		LEVOTHYROXINE		C				
		LISINOPRIL		C				
		OXYCODONE		C				
		TIMOLOL		C				
		WARFARIN		C				
Blood pressure increased								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2014	10685425	DIRECT				64 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL			GILEAD	
Fatigue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2014	10685667	EXPEDITED (15-DAY)		HO	US- GILEAD-2014-0128129		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Anxiety		HARVONI		S UNKNOWN	UNK		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2014	10685969	EXPEDITED (15-DAY)			US- GILEAD-2014-0127574	62 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea Fatigue Headache		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2014	10687524	DIRECT				57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue Influenza like illness Diarrhoea Headache		HARVONI RIBAVIRIN SOVALDI		S ORAL C C	90-400, daily, po		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2014	10687592	DIRECT	Y			37 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Diarrhoea Amenorrhoea		HARVONI		S ORAL	one tablet			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2014	10687969	DIRECT	Y			56 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue Chills Headache Hyperhidrosis		HARVONI		S ORAL	1 tablet (400mg/90mg) daily po		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2015	10620644	EXPEDITED (15-DAY)			US- GILEAD-2014-0124563		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug screen positive		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2015	10636118	EXPEDITED (15-DAY)			US- GILEAD-2014-0125284	84 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Overdose		HARVONI		S ORAL	24 DF, UNK		GILEAD	
		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2015	10653077	EXPEDITED (15-DAY)			US- GILEAD-2014-0127123		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nasopharyngitis		HARVONI		S UNKNOWN			GILEAD	
Cough		WELLBUTRIN		C				
Dysphonia								
Vomiting								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2015	10688296	EXPEDITED (15-DAY)			US- GILEAD-2014-0128477		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pollakiuria		HARVONI		S UNKNOWN	UNK		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2015	10688302	EXPEDITED (15-DAY)			US- GILEAD-2014-0128660		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Musculoskeletal pain Arthralgia Headache Myalgia		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2015	10688313	EXPEDITED (15-DAY)			US- GILEAD-2014-0128367	58 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Furuncle Depression Fatigue Nausea		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2015	10688315	EXPEDITED (15-DAY)			US- GILEAD-2014-0128371	51 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI TRAMADOL		S ORAL C	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2015	10688322	EXPEDITED (15-DAY)			US- GILEAD-2014-0128428	54 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Diarrhoea Depression Fatigue Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2015	10688325	EXPEDITED (15-DAY)			US- GILEAD-2014-0128452		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Vomiting		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2015	10688326	EXPEDITED (15-DAY)			US- GILEAD-2014-0128467	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue Anxiety Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2015	10688354	EXPEDITED (15-DAY)			US- GILEAD-2014-0128542		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Energy increased		HARVONI		S UNKNOWN	UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2015	10688355	EXPEDITED (15-DAY)			US-GILEAD-2014-0128652		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Arthropod bite		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2015	10688358	EXPEDITED (15-DAY)			US-GILEAD-2014-0128655		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Constipation		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2015	10688359	EXPEDITED (15-DAY)			US-GILEAD-2014-0128654	57 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood glucose increased		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2015	10691704	EXPEDITED (15-DAY)			US-GILEAD-2014-0128820		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hepatitis C RNA		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2015	10691705	EXPEDITED (15-DAY)			US-GILEAD-2014-0128892		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Eye discharge Skin lesion		HARVONI		S UNKNOWN	UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2015	10691708	EXPEDITED (15-DAY)			US- GILEAD-2014-0129262	58 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Influenza Chills Cough Headache Pyrexia		HARVONI		S UNKNOWN	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2015	10691710	EXPEDITED (15-DAY)			US- GILEAD-2014-0129059		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pain		HARVONI		S ORAL	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2015	10691712	EXPEDITED (15-DAY)			US- GILEAD-2014-0128967		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hot flush Nausea		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2015	10691713	EXPEDITED (15-DAY)			US- GILEAD-2014-0128965	63 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Influenza Nausea Vomiting		HARVONI		S UNKNOWN			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2015	10691714	EXPEDITED (15-DAY)			US-GILEAD-2014-0128917	59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2015	10691715	EXPEDITED (15-DAY)			US-GILEAD-2014-0129163		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Aspartate aminotransferase increased Alanine aminotransferase increased		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2015	10691717	EXPEDITED (15-DAY)			US-GILEAD-2014-0129726	47 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Agitation Anxiety Fatigue Insomnia Poor quality sleep		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2015	10691721	EXPEDITED (15-DAY)			US-GILEAD-2014-0129853	37 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Menstruation irregular Diarrhoea		HARVONI		S UNKNOWN	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2015	10691722	EXPEDITED (15-DAY)			US- GILEAD-2014-0129765	56 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Oropharyngeal pain Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2015	10691723	EXPEDITED (15-DAY)			US- GILEAD-2014-0129782	47 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Gastroenteritis viral Fatigue Insomnia Nausea		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2015	10691725	EXPEDITED (15-DAY)			US- GILEAD-2014-0129829	54 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Irritable bowel syndrome Diarrhoea Dysgeusia Dyspepsia Stomatitis		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2015	10691726	EXPEDITED (15-DAY)			US- GILEAD-2015-0130142	58 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pruritus generalised		HARVONI		S UNKNOWN	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2015	10692674	DIRECT		OT		58 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood urine present Nephrolithiasis		HARVONI		S ORAL			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2015	10695099	DIRECT	Y	HO		61 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chest pain Hypertension		HARVONI		S ORAL	one tablet		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2015	10697365	DIRECT	Y	OT		60 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Swelling face Dyspnoea Muscular weakness		HARVONI		S ORAL	1 tablet daily po		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2015	10699158	EXPEDITED (15-DAY)			US- GILEAD-2014-0129933	59 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue Diarrhoea Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2015	10699159	EXPEDITED (15-DAY)			US- GILEAD-2015-0130341		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Accidental exposure to product		HARVONI		S UNKNOW	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2015	10699160	EXPEDITED (15-DAY)			US- GILEAD-2015-0130343	54 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Somnolence		HARVONI		S ORAL	1 DF, QD		GILEAD	
Pruritus		PROPRANOLOL		C				
		XANAX		C				
		PRISTIQ		C				
		ALDACTONE 00006201/		C				
		CHANTIX		C				
		OMEPRAZOLE		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2015	10699164	EXPEDITED (15-DAY)			US- GILEAD-2015-0130363	54 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
08-Jan-2015	10699209	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2015-0130012	50 YR	Male	USA	
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>		<u>Duration</u>	<u>Manufacturer</u>
Haematemesis		HARVONI		S	UNKNOWN	UNK			GILEAD
		OCTREOTIDE		C		UNK			
		MIDAZOLAM		C		UNK			
		FENTANYL		C					
		ZOSYN		C		UNK			
		ACETAMINOPHEN		C		UNK			
		PANTOPRAZOLE		C		UNK			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
08-Jan-2015	10699214	EXPEDITED (15-DAY)			US- GILEAD-2015-0130061	67 YR	Female	USA	
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>		<u>Duration</u>	<u>Manufacturer</u>
Urine odour abnormal		HARVONI		S	UNKNOWN	UNK			GILEAD
Fatigue		URSODIOL		C		300 mg, BID			
Visual impairment		PROMACTA		C		50 mg, QD			
Dizziness		NADOLOL		C		20 mg, QD			
		SPIRONOLACTONE		C		100 mg, QD			
		L-THYROXINE 00068001/		/	C	50 µg, QD			
		SUCRALFATE		C		1 DF, QID			
		MULTIVITAMIN 07504101/		/	C	1 DF, QD			
		HYDROXYZINE HYDROCHLORIDE		C		25 mg, TID			



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2015	10699293	EXPEDITED (15-DAY)			US- GILEAD-2015-0130068	67 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2015	10700642	DIRECT	Y	HO		49 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Toxicity to various agents Agitation		RIBAVIRIN (RIBATAB) 600 MG RIBATAB DIAZEPAM(VALIUM) LITHIUM CARBONATE NAPROXEN(NAPROSYN) LEDIPAAVIR-SOFOSBUVIR		S ORAL C C C C			UNKNOWN	
Depressed level of consciousness Intentional overdose								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2015	10699313	EXPEDITED (15-DAY)			US- GILEAD-2015-0130219		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Vomiting Abdominal pain upper		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2015	10699324	EXPEDITED (15-DAY)			US- GILEAD-2015-0130282		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Influenza		HARVONI		S UNKNOWN	UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2015	10699330	EXPEDITED (15-DAY)			US- GILEAD-2015-0130318	60 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Weight decreased Decreased appetite Dizziness Fatigue Headache Nausea		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2015	10704582	DIRECT				29 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia		HARVONI		S ORAL			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2015	10704608	DIRECT				64 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pruritus generalised		HARVONI		S ORAL			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2015	10706258	DIRECT	Y	DE			Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Death		HARVONI		S ORAL			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2015	10706907	DIRECT	Y			57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nightmare Fatigue		HARVONI		S ORAL	1 tablet QD Oral		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2015	10707112	DIRECT				58 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Muscle spasms Impaired work ability Muscle spasms Pain		HARVONI		S ORAL	1; once daily	8 WEEK	GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2015	10707172	DIRECT				56 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood pressure increased Dyspnoea		HARVONI		S ORAL			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2015	10707617	DIRECT				59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue Dizziness Blood pressure increased		HARVONI ENALAPRIL HZTZ VALACYCLOVIR GAVILYTE DIAZEPAM AZITHROMYCIN CLONIDINE FOLIC ACID MAGNESIUM VITAMIND		S ORAL C C C C C C C C C C	1 tablet qd oral		GILEAD	
Pain in extremity Tinnitus								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2015	10707626	DIRECT				66 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Accidental overdose		HARVONI		S ORAL			GILEAD	
		PROPECIA		C				
		EFFEXOR		C				
		ASPIRIN		C				
		IRBESARTAN		C				
		METOPROLOL		C				
		AMLOPIPINE		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2015	10709641	DIRECT	Y			42 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S ORAL			GILEAD	
Headache								
Stomatitis								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10644526	EXPEDITED (15-DAY)			US- GILEAD-2014-0126123	34 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S UNKNOWN	1 DF, QD		GILEAD	
Nausea								
Vomiting								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10669942	EXPEDITED (15-DAY)			US- GILEAD-2014-0128077	34 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood creatine phosphokinase increased Muscle strain		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10669950	EXPEDITED (15-DAY)			US- GILEAD-2014-0128047		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pregnancy		HARVONI		S UNKNOWN	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10691727	EXPEDITED (15-DAY)			US- GILEAD-2014-0129937	58 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sleep disorder Fatigue Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10711473	EXPEDITED (15-DAY)			US- GILEAD-2015-0130435		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Arthralgia		HARVONI		S UNKNOWN			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10711528	EXPEDITED (15-DAY)			US- GILEAD-2015-0130509		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Panic attack Dyspnoea Headache Nausea		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10711863	EXPEDITED (15-DAY)			US- GILEAD-2015-0130736	73 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Mouth ulceration		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10711864	EXPEDITED (15-DAY)			US- GILEAD-2015-0130838		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Cough Asthenia Fatigue Platelet count increased Weight decreased		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10711865	EXPEDITED (15-DAY)			US- GILEAD-2015-0130741	61 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Mouth ulceration		HARVONI		S UNKNOWN			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10711866	EXPEDITED (15-DAY)			US- GILEAD-2015-0130803		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sinusitis		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10711887	EXPEDITED (15-DAY)			US- GILEAD-2015-0130894	63 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Anxiety Insomnia		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10711890	EXPEDITED (15-DAY)			US- GILEAD-2015-0130895	59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nasopharyngitis		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10712044	EXPEDITED (15-DAY)			US- GILEAD-2014-0127992		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
C-reactive protein increased Red blood cell sedimentation rate increased		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10712079	EXPEDITED (15-DAY)			US- GILEAD-2015-0130993	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Gastroesophageal reflux disease		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10712086	EXPEDITED (15-DAY)			US- GILEAD-2015-0131063		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Diarrhoea		HARVONI PEPTO-BISMOL		S UNKNOWN C	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10712799	DIRECT				60 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI VITAMIN C CYMBALTA MULTI VITAMIN PANTOPRAZOLE TRAZODONE		S ORAL C C C C C			GILEAD	
Fatigue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2015	10712952	DIRECT	Y	OT		48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Abnormal dreams Crying Nightmare		HARVONI		S ORAL	1 tablet		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2015	10714871	EXPEDITED (15-DAY)			US- GILEAD-2014-0128356		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dyspepsia		HARVONI		S			GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2015	10717632	EXPEDITED (15-DAY)			US- GILEAD-2015-0131135		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Gastroesophageal reflux disease		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2015	10717639	EXPEDITED (15-DAY)			US- GILEAD-2015-0131184	66 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Cold sweat Abdominal pain upper Abnormal faeces Nausea Retching		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2015	10717651	EXPEDITED (15-DAY)			US- GILEAD-2015-0131185	58 YR	Unknown	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nightmare Fatigue		HARVONI		S ORAL	1 DF, UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2015	10717660	EXPEDITED (15-DAY)		OT	CA- GILEAD-2015-0131419	58 YR	Male	CAN
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nephrolithiasis		HARVONI		S UNKNOWN	UNK		GILEAD	
Chromaturia		ROSUVASTATIN		S UNKNOWN	UNK			
Cough								
Diarrhoea								
Influenza								
Muscle spasms								
Oropharyngeal pain								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2015	10717664	EXPEDITED (15-DAY)			US- GILEAD-2015-0131227	58 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Localised intraabdominal fluid collection		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2015	10717672	EXPEDITED (15-DAY)			US- GILEAD-2015-0131240	56 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chills		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2015	10723560	DIRECT	Y	DE		59 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Convulsion		HARVONI		S ORAL	1-2-15 only		GILEAD	
Cardiac arrest								
Respiratory failure								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2015	10723792	DIRECT		LT,OT		53 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hypertension		HARVONI		S ORAL	1 QD Oral		GILEAD	
Hypoaesthesia oral		CARVEDILOL		C				
Dizziness								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2015	10721645	EXPEDITED (15-DAY)			US- GILEAD-2015-0132046		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Therapeutic response changed		HARVONI		S UNKNOWN			GILEAD	
Fatigue								
Headache								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2015	10721777	EXPEDITED (15-DAY)			US- GILEAD-2015-0131289		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea		HARVONI		S UNKNOWN			GILEAD	
Feeling abnormal		PLAQUENIL SULFATE		C				



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2015	10722176	EXPEDITED (15-DAY)		DE,OT	IE- GILEAD-2015-0132637	50 YR	Male	IRL
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Sepsis		HARVONI		S	ORAL	1 DF, QD		GILEAD
Lactic acidosis		TRUVADA		C		UNK		GILEAD
Pulmonary embolism		COPEGUS		C		UNK		
Cardiac arrest		SEPTRIN		C		UNK		
		THIAMINE		C				
		CENTRUM 02217401/		/	C			
		FLORINEF		C				
		HYDROCORTONE 00028601/		/	C			
		ISENTRESS		C				
		LAXOSE		C				
		SEKOT 00142201/		/	C			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2015	10722222	EXPEDITED (15-DAY)			US- GILEAD-2015-0131551		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Fungal infection		HARVONI		S	UNKNOWN	UNK		GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2015	10722231	EXPEDITED (15-DAY)			US- GILEAD-2015-0131402	58 YR	Unknown	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Hordeolum		HARVONI		S	UNKNOWN	UNK		GILEAD
Arthralgia								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2015	10722361	EXPEDITED (15-DAY)			US- GILEAD-2015-0131837		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hypertension		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2015	10722366	EXPEDITED (15-DAY)			US- GILEAD-2015-0131881	61 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2015	10722375	EXPEDITED (15-DAY)			US- GILEAD-2015-0131937		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash erythematous Pruritus		HARVONI PLAQUENIL 00072602/		S UNKNOWN C			GILEAD	
Sleep disorder due to a general medical condition								



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2015	10669939	EXPEDITED (15-DAY)			US- GILEAD-2014-0128008	57 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Overdose		HARVONI		S UNKNOWN	2 DF, QD		GILEAD	
		HARVONI		S UNKNOWN	1 UNK, UNK		GILEAD	
		FERROUS SULFATE		C	UNK			
		VITAMIN B COMPLEX		C	UNK			
		ZESTORETIC		C	UNK			
		KEPPRA		C	UNK			
		RIVASTIGMINE		C	UNK			
		SPIRONOLACTONE		C	UNK			
		METFORMIN		C	UNK			
		FUROSEMIDE		C	UNK			
		LEXAPRO		C	UNK			
		FOLIC ACID		C	UNK			
		COGENTIN		C	UNK			
		XANAX		C	UNK			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2015	10711479	EXPEDITED (15-DAY)		HO	US- GILEAD-2015-0130448		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Toxicity to various agents		HARVONI		S UNKNOWN	UNK		GILEAD	
Drug interaction		DIGOXIN		S UNKNOWN	UNK			



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2015	10726267	DIRECT				65 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Weight decreased Constipation Dehydration Fatigue		HARVONI		S ORAL	1 tablet daily po		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2015	10726581	DIRECT				46 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Vomiting Dizziness Visual impairment		HARVONI		S ORAL	1 tablet, daily, po		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2015	10730466	DIRECT				60 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood pressure increased		HARVONI		S ORAL	1 pill once daily taken by mouth		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2015	10647571	EXPEDITED (15-DAY)			US- GILEAD-2014-0126407	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pain		HARVONI		S ORAL	1 DF, QD		GILEAD	
Dry skin		PROTONIX		C				
Rash		GABAPENTIN		C				
Pruritus		PREMARIN		C				
Pruritus generalised		LYRICA		C				
		PROVIGIL	/	C				
		01265601/						
		VYVANSE		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2015	10729433	DIRECT	Y	OT		59 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood pressure increased		HARVONI		S ORAL	Harvoni QD Oral			
		METOPROLOL TARTRATE		C				
		AMLOPIDINE		C				
		CLONAZEPAM		C				
		TACROLIMUS		C				
		MYCOPHENOLATE MOFETIL		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2015	10729525	DIRECT	Y			63 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia		HARVONI		S ORAL			GILEAD	
Fatigue								
Pain								



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2015	10729585	DIRECT				67 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI 90-400MG GILEAD SCIENCES		S ORAL			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2015	10729830	DIRECT	Y				Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Oral candidiasis Stomatitis		HARVONI		S ORAL	1, qd, oral		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2015	10687986	EXPEDITED (15-DAY)			US- GILEAD-2014-0127854		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Aggression Gastroesophageal reflux disease Insomnia Nausea		HARVONI		S			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2015	10731118	EXPEDITED (15-DAY)			US- GILEAD-2015-0132274	63 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Alopecia		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2015	10731125	EXPEDITED (15-DAY)			US- GILEAD-2015-0131976	58 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pain		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2015	10731128	EXPEDITED (15-DAY)			US- GILEAD-2015-0132052	55 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Insomnia		HARVONI		S ORAL	1 DF, QD			GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2015	10731129	EXPEDITED (15-DAY)			US- GILEAD-2015-0132827	40 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Rash		HARVONI		S UNKNOWN	UNK			GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2015	10731172	EXPEDITED (15-DAY)			US- GILEAD-2015-0132243		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Accidental overdose		HARVONI		S UNKNOWN	1 DF, UNK			GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2015	10736151	DIRECT		OT			Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Vomiting Aphagia Headache Insomnia		HARVONI		S ORAL	1 tab daily po			GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2015	10734163	EXPEDITED (15-DAY)			US- GILEAD-2015-0132187	56 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Fatigue		HARVONI		S ORAL	1 DF, QD			GILEAD



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2015	10736427	DIRECT	Y	DE		60 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hepatic failure		HARVONI		S ORAL	1		GILEAD	
		CITALOPRAM		C				
		FUROSEMIDE		C				
		LACTULOSE		C				
		MULTIVITAMIN		C				
		NADOLOL		C				
		NORCO		C				
		PANTOPRAZOLE		C				
		SPIRONOLACTONE		C				
		VITAMIN B12		C				
		VITAMIN C		C				
		VITAMIN D		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2015	10738282	DIRECT		OT		68 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pain in extremity Palpitations		HARVONI		S ORAL			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2015	10738312	DIRECT		OT		49 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Peripheral swelling		HARVONI		S				GILEAD
Peripheral swelling		AMITIZA		C				
		MORPHINE		C				
		LOSARTAN		C				
		ONDANSETRON		C				
		ALPRAZOLAM		C				
		NITROFURANTOIN		C				
		AMIODIPINE		C				
		TIZANIDINE		C	ORAL			
Local swelling								
Peripheral swelling								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2015	10738326	DIRECT	Y	OT		60 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Platelet count decreased		HARVONI		S	ORAL	one tablet, QD, Oral		GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2015	10738363	DIRECT	Y	OT		56 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Dyspnoea		HARVONI		S	ORAL	one tablet		GILEAD
Back pain								
Chest discomfort								
Fatigue								
Insomnia								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2015	10740758	DIRECT	Y			61 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
White blood cell count decreased		HARVONI		S	ORAL	one tablet		GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2015	10741259	DIRECT		HO		57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Encephalopathy		LEDIPASVIR-SOFOSBUVIR (HARVONI) 90-400MG GILEAD SCIENCES, INC.		S	ORAL			GILEAD
Treatment noncompliance		ELAVIL		C				
		CHOLECALCIFEROL		C				
		NEXIUM		C				
		LASIX		C				
		XODOL		C				
		ZOFRAN		C				
		ALDACTONE		C				
		ROXICODONE		C				
Ammonia increased								
Condition aggravated								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2015	10741736	DIRECT	Y			58 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Blood pressure fluctuation		HARVONI		S	ORAL	one tablet QD Oral		GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2015	10742327	DIRECT		HO,LT		63 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Convulsion		HARVONI		S	ORAL	once daily		
Hypotension								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10669954	EXPEDITED (15-DAY)			US-GILEAD-2014-0128334	55 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia		HARVONI		S ORAL	1 DF, QD		GILEAD	
Headache								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10681308	EXPEDITED (15-DAY)		HO	US-GILEAD-2014-0128650		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Lung disorder		HARVONI		S UNKNOWN	UNK		GILEAD	
Rash generalised		RIBAVIRIN		S UNKNOWN	UNK			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10717652	EXPEDITED (15-DAY)			US-GILEAD-2015-0131186	55 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Vision blurred		HARVONI		S ORAL	1 DF, QD		GILEAD	
Visual acuity reduced		LASIX	/00032601/	C UNKNOWN	UNK			
		SPIRONOLACTONE		C UNKNOWN	UNK			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10737993	EXPEDITED (15-DAY)			US-GILEAD-2015-0132575		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Arthropathy		HARVONI		S UNKNOWN			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10738319	EXPEDITED (15-DAY)			US- GILEAD-2015-0132150	58 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Tinnitus Dizziness Headache Irritability Nausea		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10738442	EXPEDITED (15-DAY)			US- GILEAD-2015-0132312		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Arthritis		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10738452	EXPEDITED (15-DAY)			US- GILEAD-2015-0133864	35 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Weight increased Therapeutic response changed		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10738939	EXPEDITED (15-DAY)			US- GILEAD-2015-0132490		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chromaturia		HARVONI		S UNKNOWN	UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10738941	EXPEDITED (15-DAY)			US- GILEAD-2015-0132334	64 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nightmare		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10738946	EXPEDITED (15-DAY)			US- GILEAD-2015-0132348		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Photophobia		HARVONI		S UNKNOWN			GILEAD	
		BRIMONIDINE		C				
		PREDNISOLONE		C				
		DORZOLAMIDE		C				
		LATANOPROST		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10738947	EXPEDITED (15-DAY)			US- GILEAD-2015-0132285		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Night sweats		HARVONI		S UNKNOWN	UNK		GILEAD	
Fatigue								
Somnolence								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10738958	EXPEDITED (15-DAY)			US- GILEAD-2015-0132494	50 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
Nausea								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739035	EXPEDITED (15-DAY)			US- GILEAD-2015-0132351	64 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739053	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2015-0133443		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Convulsion		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739067	EXPEDITED (15-DAY)			US- GILEAD-2015-0132396		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pallor Heart rate irregular		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739082	EXPEDITED (15-DAY)			US- GILEAD-2015-0132455	61 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Irritability		HARVONI RIBAVIRIN		S ORAL C	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739098	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0133396	33 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Suicidal ideation Abnormal behaviour		HARVONI		S UNKNOWN	UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739108	EXPEDITED (15-DAY)			US- GILEAD-2015-0132664	49 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739114	EXPEDITED (15-DAY)			US- GILEAD-2015-0133313	57 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739116	EXPEDITED (15-DAY)			US- GILEAD-2015-0133333	61 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dyspepsia		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739127	EXPEDITED (15-DAY)			US- GILEAD-2015-0133009	54 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Stress Anxiety Depressed mood Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739193	EXPEDITED (15-DAY)			US- GILEAD-2015-0133187	30 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Diarrhoea		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739206	EXPEDITED (15-DAY)			US- GILEAD-2015-0133251	60 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739208	EXPEDITED (15-DAY)			US- GILEAD-2015-0133215	55 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739226	EXPEDITED (15-DAY)			US- GILEAD-2015-0133135	59 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Body temperature decreased Feeling cold		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739239	EXPEDITED (15-DAY)			US- GILEAD-2015-0133261	64 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dehydration Blood creatinine increased Creatinine renal clearance decreased		HARVONI LIRAGLUTIDE		S UNKNOWN C	UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739249	EXPEDITED (15-DAY)			US-GILEAD-2015-0133308		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hordeolum Arthralgia		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739259	EXPEDITED (15-DAY)			US-GILEAD-2015-0133331		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Oral candidiasis		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739284	EXPEDITED (15-DAY)			US-GILEAD-2015-0133379		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue Abdominal pain upper Diarrhoea Vomiting		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739291	EXPEDITED (15-DAY)			US-GILEAD-2015-0133314	65 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pruritus Rash		HARVONI		S UNKNOWN	UNK		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739297	EXPEDITED (15-DAY)			US- GILEAD-2015-0133611		Unknown	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pyrexia Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739301	EXPEDITED (15-DAY)			US- GILEAD-2015-0133392		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Malaise Fatigue Asthenia		HARVONI RIBAVIRIN		S UNKNOWN C	UNK UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739307	EXPEDITED (15-DAY)			US- GILEAD-2015-0133424	67 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739312	EXPEDITED (15-DAY)			US- GILEAD-2015-0133650		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood count abnormal Fatigue Unevaluable event		HARVONI RIBAVIRIN		S ORAL C	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10739345	EXPEDITED (15-DAY)			US- GILEAD-2015-0133875	55 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10744699	DIRECT	Y			61 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pain in extremity Peripheral swelling		HARVONI		S ORAL	1 TABLET, DAILY, PO		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10744726	DIRECT				64 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Weight decreased		HARVONI LISINOPRIL		S ORAL C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10744750	DIRECT	Y			52 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI 90MG-400MG		S ORAL	1 TAB, QD, PO			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2015	10745442	DIRECT	Y	HO		53 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fluid retention Localised oedema Scrotal oedema		HARVONI		S ORAL	1			



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2015	10741839	EXPEDITED (15-DAY)			US- GILEAD-2015-0133145		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Facial paresis Abdominal discomfort Hyperhidrosis Lacrimation increased Nausea		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2015	10741884	EXPEDITED (15-DAY)			US- GILEAD-2015-0133281	59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dysgeusia Sleep disorder Decreased appetite Fatigue Memory impairment		HARVONI RIBAPAK		S ORAL C	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2015	10741904	EXPEDITED (15-DAY)			US- GILEAD-2015-0133305	52 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2015	10742008	EXPEDITED (15-DAY)			US- GILEAD-2015-0133651	59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hypertension Blood glucose increased Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2015	10742770	EXPEDITED (15-DAY)			US- GILEAD-2015-0133969		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Overdose		HARVONI		S UNKNOWN	2 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2015	10742796	EXPEDITED (15-DAY)			US- GILEAD-2015-0133518	65 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Limb discomfort Fatigue		HARVONI		S UNKNOWN	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2015	10743109	EXPEDITED (15-DAY)			US- GILEAD-2015-0133413		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Alopecia		HARVONI VITAMINS NOS		S UNKNOWN C			GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2015	10743161	EXPEDITED (15-DAY)			US- GILEAD-2015-0133895		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Epistaxis		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2015	10743226	EXPEDITED (15-DAY)			US- GILEAD-2015-0133896		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Epistaxis		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2015	10743232	EXPEDITED (15-DAY)			US- GILEAD-2015-0134117		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Feeling abnormal Headache		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2015	10743256	EXPEDITED (15-DAY)			US- GILEAD-2015-0133905	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pyrexia Sinusitis		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2015	10745791	DIRECT		OT		51 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI 90-400MG GILEAD SCIENCES		S ORAL			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2015	10745790	EXPEDITED (15-DAY)		OT	CA- GILEAD-2015-0133678		Male	CAN
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Urinary retention		HARVONI		S	UNKNOWN	UNK		GILEAD
Peripheral swelling		TRUVADA		C				
Somnolence		ATAZANAVIR W/RITONAVIR		C				
		METHADONE		C				
		ZOPLICONE		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2015	10746519	EXPEDITED (15-DAY)			US- GILEAD-2015-0134101	60 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Tooth infection		HARVONI		S	UNKNOWN			GILEAD
		RIBAVIRIN		C				
		CLINDAMYCIN		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2015	10746521	EXPEDITED (15-DAY)			US- GILEAD-2015-0134056	62 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Nasopharyngitis		HARVONI		S	UNKNOWN	UNK		GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2015	10746523	EXPEDITED (15-DAY)			US- GILEAD-2015-0134412	62 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Headache		HARVONI		S	ORAL	1 DF, QD		GILEAD



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2015	10746525	EXPEDITED (15-DAY)			US- GILEAD-2015-0134390	49 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Anxiety Depression		HARVONI		S ORAL	400 mg, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2015	10746526	EXPEDITED (15-DAY)			US- GILEAD-2015-0134324		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue Tinnitus		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2015	10746527	EXPEDITED (15-DAY)		HO,OT	IE- GILEAD-2015-0134165	70 YR	Female	IRL
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Ascites		HARVONI		S ORAL	1 DF, QD		GILEAD	
Pneumonia		RIBAVIRIN		S ORAL	1 DF, QD			
Cellulitis		OMEPRAZOLE		C				
		FLUOXETINE		C				
		CEFUROXIME		C				
		CO-TRIMOXAZOLE		C				
		SPIRONOLACTONE		C				
		TEMAZEPAM		C				
		FRUSEMIDE	/	C				
		00032601/						



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2015	10746528	EXPEDITED (15-DAY)			US- GILEAD-2015-0134273	52 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dyspnoea		HARVONI ALBUTEROL SULFATE		S UNKNOWN C	1 DF, UNK UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2015	10746532	EXPEDITED (15-DAY)			US- GILEAD-2015-0134102	60 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Abdominal pain		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2015	10746533	EXPEDITED (15-DAY)			US- GILEAD-2015-0133817		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood thyroid stimulating hormone increased		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2015	10748880	DIRECT	Y	OT		52 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Aortic stenosis		HARVONI 90MG-400MG		S ORAL	1 tablet, qd, oral		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2015	10748385	EXPEDITED (15-DAY)			US- GILEAD-2015-0133545	62 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash		HARVONI		S ORAL	1 DF, QD		GILEAD	
		TACROLIMUS		C				
		CARVEDILOL		C	12.5 mg, UNK			
		LOSARTAN		C				
		CREON		C				
		FISH OIL		C				
		LANTUS		C				
		CALCIUM		C				
		PRAVASTATIN		C				
		NOVOLOG		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2015	10750839	DIRECT					Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chest pain		HARVONI 90-400MG TAB GILEAD SCIENCES		S ORAL			GILEAD	
Abdominal pain upper								
Dyspepsia								
Dyspnoea								
Fatigue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2015	10751165	DIRECT				64 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Constipation		HARVONI 90/400MG GILEAD		S ORAL	90/400mg (1 tablet) once daily by mouth		GILEAD	
Ear disorder								
Tinnitus								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2015	10739253	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0133332	66 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Cognitive disorder Fatigue Feeling abnormal Headache		HARVONI		S	UNKNOWN	UNK		GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2015	10750533	EXPEDITED (15-DAY)		HO	IE-ROCHE-1528362	61 YR	Male	IRL
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Haemoglobin decreased		Copegus		S	UNKNOWN	400 mg in the morning and and 600 mg in the evening		
Blood phosphorus decreased		HARVONI		S	ORAL			
Blood potassium decreased		TRUVADA		C				
		PREZISTA		C				
		NORVIR		C				
		LANSOPRAZOLE		C				
		SEPTRIN		C				
		METHADONE		C				
		LAXOSE		C				
		FUROSEMIDE		C				
		Diazepam		C	UNKNOWN			
		THIAMINE		C				



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2015	10752227	EXPEDITED (15-DAY)		HO,OT	IE- GILEAD-2015-0134166	45 YR	Female	IRL
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Ascites		HARVONI		S UNKNOW	1 DF, QD		GILEAD	
		RIBAVIRIN		S ORAL	1 DF, QD			
		RIFAXIMIN		C				
		TRANEXAMIC ACID		C				
		DOVOBET		C				
		URSOFALK		C				
		CIPROFLOXACIN		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2015	10754234	DIRECT	Y				Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug hypersensitivity		HARVONI 90/400 MG GILEAD		S ORAL	1 tablet		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2015	10754771	DIRECT		OT			Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI 90-400MG GILEAD SCIENCES		S ORAL			GILEAD	
Feeling abnormal		THYROID (ARMOUR) 2G (120 MG) TABS		C				
Gastroesophageal reflux disease		PRILOSEC		C				
Feeling abnormal		CITALOPRAM		C				
Condition aggravated								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2015	10755150	DIRECT					Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Headache	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD		
	ATORVASTATIN		C					
	FLUVIRIN MULTIDOSE VIAL		C					
	METFORMIN ER		C					
	INCIVEK		C					
	FISH OIL		C					
	PEGASYS		C					
	GLUCOSAMINE CHONDROITIN		C					
	RIBAVIRIN		C					
	FIN FISH OIL X/S ENT CD		C					
	CALCIUM		C					
	VITAMIN D		C					
	DESONIDE		C					
	CONTOUR NEXT TEST STRIPS		C					
	MICROLET COLORED LANCETS		C					
Constipation								



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2015	10755225	DIRECT				57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI 90-400MG GILEAD SCIENCES		S ORAL			GILEAD	
		VICODIN		C				
Mood altered		VIVELLE-DOT		C				
Decreased appetite		CALCIUM		C				
Rash erythematous		AMBIEN		C				
		IMITREX		C				
Crying								
Fatigue								
Migraine								
Rash								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2015	10704986	EXPEDITED (15-DAY)		DE,HO,OT	US-GILEAD-2015-0131119	52 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Death		HARVONI		S UNKNOWN	UNK		GILEAD	
Acute hepatic failure								
Disease progression								
Hepatic cirrhosis								
Jaundice								



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2015	10753861	EXPEDITED (15-DAY)		HO,OT	IE-ROCHE-1528375	70 YR	Female	IRL
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Ascites		Ribavirin		S ORAL				
Pneumonia		HARVONI		S ORAL				
Cellulitis		OMEPRAZOLE		C				
		FLUOXETINE		C				
		CEFUROXIME		C				
		COTRIMOXAZOLE		C				
		SPIRONOLACTONE		C				
		TEMAZEPAM		C				
		FRUSEMIDE		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2015	10756335	EXPEDITED (15-DAY)			US- GILEAD-2015-0133426		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2015	10756337	EXPEDITED (15-DAY)			US- GILEAD-2015-0133959	56 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood pressure increased		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	
		CARVEDILOL		C	3.25 mg, UNK			



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2015	10756430	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0134496	70 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Renal impairment Blood creatinine increased Blood urea increased Decreased appetite Weight decreased		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2015	10756440	EXPEDITED (15-DAY)			US- GILEAD-2015-0134533		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Thyroid function test abnormal Product packaging quantity issue		HARVONI		S UNKNOWN	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10739185	EXPEDITED (15-DAY)			US- GILEAD-2015-0133065	61 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nasal congestion Cough		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10739209	EXPEDITED (15-DAY)			US- GILEAD-2015-0132862		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Peripheral swelling Rash		HARVONI		S UNKNOWN	UNK		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10743237	EXPEDITED (15-DAY)			US- GILEAD-2015-0134052	64 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dry mouth		HARVONI		S UNKNOWN	UNK		GILEAD	
Epigastric discomfort								
Fatigue								
Insomnia								
Oral disorder								
Product measured potency issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759377	EXPEDITED (15-DAY)			US- GILEAD-2015-0133057	49 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash erythematous		HARVONI		S UNKNOWN	UNK		GILEAD	
Peripheral swelling		AMITIZA		C	UNK			
		IRBESARTAN		C	UNK			
		MORPHINE		C	UNK			
		OXYCODONE		C	UNK			
		MACROGOL		C	UNK			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759397	EXPEDITED (15-DAY)			US- GILEAD-2015-0134317		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Oropharyngeal pain		HARVONI		S UNKNOWN	UNK		GILEAD	
Cough								
Social problem								



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759399	EXPEDITED (15-DAY)			US- GILEAD-2015-0134213		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Cough		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759415	EXPEDITED (15-DAY)			US- GILEAD-2015-0133977		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood glucose decreased Dizziness		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759502	EXPEDITED (15-DAY)			US- GILEAD-2015-0134016	55 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759518	EXPEDITED (15-DAY)			US- GILEAD-2015-0134121	52 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759524	EXPEDITED (15-DAY)			US- GILEAD-2015-0132966	55 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759529	EXPEDITED (15-DAY)			US- GILEAD-2015-0134442		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759537	EXPEDITED (15-DAY)			US- GILEAD-2015-0134450		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nasopharyngitis Chills Headache Influenza Pyrexia Upper respiratory tract congestion		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759631	EXPEDITED (15-DAY)			US- GILEAD-2015-0134443		Unknown	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dizziness Feeling drunk Vertigo		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759648	EXPEDITED (15-DAY)			US- GILEAD-2015-0134290	71 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Back disorder		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759657	EXPEDITED (15-DAY)			US- GILEAD-2015-0134596	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Spinal pain Arthralgia Decreased interest Depression Fatigue Neck pain		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759695	EXPEDITED (15-DAY)			US- GILEAD-2015-0134463		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hypertension		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759703	EXPEDITED (15-DAY)			US- GILEAD-2015-0134484		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chills Arthralgia Fatigue Joint swelling Myalgia		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759734	EXPEDITED (15-DAY)			US- GILEAD-2015-0134488	65 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759735	EXPEDITED (15-DAY)			US- GILEAD-2015-0134498		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Gout		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759758	EXPEDITED (15-DAY)			US- GILEAD-2015-0134611		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nasopharyngitis		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10759773	EXPEDITED (15-DAY)			US- GILEAD-2015-0134497		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Abdominal pain upper		HARVONI ZANTAC		S UNKNOWN C			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10761129	DIRECT	Y	OT		55 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue Rash		HARVONI		S ORAL			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2015	10761221	DIRECT	Y	OT		46 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Lip swelling		HARVONI		S ORAL	1 tablet Once daily By mouth		GILEAD	
Eye swelling								
Rash generalised								
Type IV hypersensitivity reaction								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10717186	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0131160	64 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Ascites		HARVONI		S ORAL	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10731121	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0131973	58 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hallucination, auditory		HARVONI		S ORAL	1 DF, UNK		GILEAD	
Agitation								
Distractibility								
Insomnia								
Soliloquy								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10763101	EXPEDITED (15-DAY)			US-GILEAD-2015-0134794	52 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
Fatigue								



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10763129	EXPEDITED (15-DAY)			US- GILEAD-2015-0135033	47 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Accidental overdose		HARVONI		S UNKNOWN	2 DF, Once		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10763148	EXPEDITED (15-DAY)			US- GILEAD-2015-0134942	53 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Disturbance in attention Headache Insomnia		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10763160	EXPEDITED (15-DAY)			US- GILEAD-2015-0135140		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sinusitis Nasopharyngitis		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10763167	EXPEDITED (15-DAY)			US- GILEAD-2015-0135198	63 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash		HARVONI		S UNKNOWN	UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10763185	EXPEDITED (15-DAY)			US- GILEAD-2015-0135196	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Nausea		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10763198	EXPEDITED (15-DAY)			US- GILEAD-2015-0135130		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Viral load		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10763209	EXPEDITED (15-DAY)			US- GILEAD-2015-0135474		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI SUBOXONE AMBIEN		S UNKNOWN C C	UNK UNK UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10763888	EXPEDITED (15-DAY)			US- GILEAD-2015-0135304	49 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue Headache		HARVONI ADVIL	/00109201/	S ORAL C	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10764030	EXPEDITED (15-DAY)			US-GILEAD-2015-0134974	55 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pain		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10764077	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0134424	65 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rheumatoid arthritis		HARVONI		S ORAL	1 DF, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10764084	EXPEDITED (15-DAY)			US-GILEAD-2015-0134745	44 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hypertension		HARVONI AMLODIPINE		S ORAL C ORAL	1 DF, UNK 1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10764090	EXPEDITED (15-DAY)			US-GILEAD-2015-0135496		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Increased appetite		HARVONI		S UNKNOWN	UNK		GILEAD	
Weight increased		TIZANIDINE		S UNKNOWN	4 mg, QD			
Drug effect decreased		MORPHINE SULFATE		C	UNK			
Abdominal pain upper								
Fatigue								
Headache								
Irritability								
Nausea								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10764955	DIRECT					Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea		HARVONI		S ORAL			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2015	10765810	DIRECT	Y	HO		46 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Influenza		HARVONI 90/400MG GILEAD		S ORAL	one tablet		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2015	10699069	EXPEDITED (15-DAY)			US- GILEAD-2015-0130799	59 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Bronchitis		HARVONI		S ORAL	1 DF, QD		GILEAD	
Potentiating drug interaction		Z-PAK		S UNKNOWN	UNK			
Fatigue		XIFAXAN		C				
Chest discomfort								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2015	10699322	EXPEDITED (15-DAY)		DE,HO,OT	US- GILEAD-2015-0130275	59 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Cardiac arrest		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	
Convulsion		AMIODARONE		C				
Hyponatraemia		NADOLOL		C				
Hypoalbuminaemia		PRAMIPEXOLE		C				
Hepatic enzyme increased		OMEPRAZOLE		C				
Leukocytosis		LASIX		/00032601/ C				
Thrombocytopenia		SILYBUM MARIANUM		C				
Coagulopathy								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2015	10759646	EXPEDITED (15-DAY)			US- GILEAD-2015-0134194	51 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia		HARVONI		S ORAL	1 DF, QD		GILEAD	
Nausea		LASIX	/00032601/	C				
Headache		ADVIL	/00109201/	C				
Fatigue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2015	10767721	EXPEDITED (15-DAY)			US- GILEAD-2015-0135061		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Gingival disorder		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	
Back disorder								
Fatigue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2015	10767744	EXPEDITED (15-DAY)			US- GILEAD-2015-0135325	59 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2015	10767745	EXPEDITED (15-DAY)			US- GILEAD-2015-0135385	31 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Anxiety		HARVONI		S ORAL	1 DF, QD		GILEAD	
Fatigue								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2015	10767764	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2015-0135639	53 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hepatic cirrhosis		HARVONI		S UNKNOWN	UNK		GILEAD	
Gastrointestinal haemorrhage		PROTONIX		C	UNK			
Anaemia								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2015	10776155	DIRECT		OT		58 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI 90/400 MG GILEAD		S ORAL	1 tab daily oral		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2015	10746524	EXPEDITED (15-DAY)			US- GILEAD-2015-0133695	51 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Anxiety		HARVONI		S ORAL	1 DF, QD		GILEAD	
Fatigue								
Headache								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2015	10770915	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0135848		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dermatitis bullous		HARVONI		S UNKNOWN	UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2015	10771816	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0135510	58 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hypertension Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2015	10771949	EXPEDITED (15-DAY)			US- GILEAD-2015-0135709		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hepatitis C virus test positive		HARVONI		S	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2015	10771981	EXPEDITED (15-DAY)			US- GILEAD-2015-0135713		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hepatitis C virus test positive		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2015	10772027	EXPEDITED (15-DAY)			US- GILEAD-2015-0135561	57 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI HARVONI		S ORAL S	1 DF, QD UNK		GILEAD GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2015	10772120	EXPEDITED (15-DAY)			US- GILEAD-2015-0135683	66 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood pressure increased		HARVONI		S UNKNOWN	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
06-Feb-2015	10772269	EXPEDITED (15-DAY)		DE,OT	US- GILEAD-2015-0136217		Male	USA	
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>		<u>Duration</u>	<u>Manufacturer</u>
Death		HARVONI		S	UNKNOWN				GILEAD
		HARVONI		S					GILEAD
		COMPLERA		S	UNKNOWN				GILEAD
		COMPLERA		S					GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
06-Feb-2015	10780312	DIRECT	Y			57 YR	Female	USA	
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>		<u>Duration</u>	<u>Manufacturer</u>
Hypertension		HARVONI		S	ORAL				GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Feb-2015	10717635	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0131149	65 YR	Male	USA	
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>		<u>Duration</u>	<u>Manufacturer</u>
Hyperglycaemia		HARVONI		S	ORAL	1 DF, QD			GILEAD
Drug interaction		LANTUS		S	UNKNOWN	50 IU, QHS			
		METFORMIN		S	UNKNOWN	500 Unknown, BID			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Feb-2015	10727394	EXPEDITED (15-DAY)		HO	US- GILEAD-2015-0132493		Male	USA	
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>		<u>Duration</u>	<u>Manufacturer</u>
Abdominal pain		HARVONI		S	UNKNOWN	UNK			GILEAD
		RIBAVIRIN		S	UNKNOWN	UNK			



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10738047	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2015-0133623	73 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Ascites		HARVONI		S	ORAL	1 DF, QD		GILEAD
Oedema		ABILIFY		C				
Atelectasis		ALDACTONE 00006201/		/	C UNKNOWN	25 mg, UNK		
Oedema peripheral		ALDACTONE 00006201/		/	C UNKNOWN	50 UNK, UNK		
Arthralgia		ASPIRIN 00002701/		/	C			
		AVODART			C UNKNOWN	0.5 mg, UNK		
		CRESTOR			C UNKNOWN	UNK		
		KLONOPIN			C UNKNOWN	UNK		
		LEXAPRO			C UNKNOWN	UNK		
		VITAMIN D 00107901/		/	C UNKNOWN	UNK		
		B12		/00056201/	C UNKNOWN	UNK		
		MULTIVITAMIN 07504101/		/	C UNKNOWN	UNK		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10763232	EXPEDITED (15-DAY)			US- GILEAD-2015-0135355	55 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Local swelling		HARVONI		S	ORAL	1 DF, QD		GILEAD
Headache								
Pain of skin								
Pruritus								
Skin disorder								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10776561	EXPEDITED (15-DAY)			US- GILEAD-2015-0135566	63 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10776941	EXPEDITED (15-DAY)		OT	DE- GILEAD-2015-0135391		Female	DEU
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Helminthic infection Zoonosis		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10776968	EXPEDITED (15-DAY)			US- GILEAD-2015-0135615		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Balance disorder Balance disorder Nausea		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10776997	EXPEDITED (15-DAY)			US- GILEAD-2015-0135627	63 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Decreased interest		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10777156	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0135716	56 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Retinal detachment		HARVONI		S UNKNOWN	UNK		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10777170	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0135721		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Atrial fibrillation		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10777375	EXPEDITED (15-DAY)			US- GILEAD-2015-0135674	53 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10777392	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2015-0135835	66 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Gastrointestinal haemorrhage		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10777511	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0135900	44 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Angioedema		HARVONI		S UNKNOWN	UNK		GILEAD	
Rash generalised		LEVOTHYROXINE		C	UNK			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10777757	EXPEDITED (15-DAY)			US- GILEAD-2015-0135787	55 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Depression		HARVONI		S ORAL	1 DF, UNK		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10777760	EXPEDITED (15-DAY)			US- GILEAD-2015-0135865	66 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood glucose increased Anxiety		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10777796	EXPEDITED (15-DAY)			US- GILEAD-2015-0135937	63 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Vertigo		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10777878	EXPEDITED (15-DAY)			US- GILEAD-2015-0135893		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Swollen tongue		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10777880	EXPEDITED (15-DAY)			US- GILEAD-2015-0135918	58 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Stomatitis Anxiety Fatigue Headache Insomnia		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10777883	EXPEDITED (15-DAY)			US- GILEAD-2015-0135938		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pyrexia Arthralgia Chills White blood cell count increased		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10777894	EXPEDITED (15-DAY)			US- GILEAD-2015-0135958	52 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10777901	EXPEDITED (15-DAY)			US- GILEAD-2015-0135724		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Malaise Hypertension		HARVONI OMEPRAZOLE		S UNKNOWN S UNKNOWN	1 DF, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10778108	EXPEDITED (15-DAY)			US- GILEAD-2015-0136316		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash erythematous Inflammation		HARVONI		S UNKNOWN	UNK, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10778110	EXPEDITED (15-DAY)			US- GILEAD-2015-0136279	60 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nervousness		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10778131	EXPEDITED (15-DAY)			US- GILEAD-2015-0135658		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash pruritic		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10778154	EXPEDITED (15-DAY)			US- GILEAD-2015-0136236		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Mouth swelling Speech disorder		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10778155	EXPEDITED (15-DAY)			US- GILEAD-2015-0136152		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Confusional state Disorientation		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10778156	EXPEDITED (15-DAY)			US- GILEAD-2015-0136013	59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Depression		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10781806	DIRECT	Y			65 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Anxiety			HARVONI 90-400MG GILEAD SCIENCES	S ORAL	90-400 mg		GILEAD	
Condition aggravated								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10782719	DIRECT	Y	HO		54 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rhabdomyolysis Blood urine present Oral herpes Upper respiratory tract infection			HARVONI 90/400 MG GILEAD	S			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2015	10782755	DIRECT	Y	HO		57 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug withdrawal convulsions Metabolic acidosis			LEDIPASVIR-SOFOSBUVIR (HARVONI) ALPRAZOLAM (XANAX) 1MG/3X PER DAY CARISOPRODOL (SOMA) DEXTROAMPHETAMINE-AMPHETAMINE (AMPHETAMINE-DEXTROAMPHETAMINE) ESCITALOPRAM (LEXAPRO) OXYCODONE (ROXICODONE) OXYMORPHONE (OPANA ER) ZOLDIPEM (AMBIEN)	S ORAL C C C C C C C			GILEAD	
Drug dose omission								



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2015	10712085	EXPEDITED (15-DAY)			US- GILEAD-2015-0131007	62 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Vllth nerve paralysis		HARVONI		S UNKNOWN	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2015	10781254	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0136136		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Renal failure acute		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2015	10783670	EXPEDITED (15-DAY)			US- GILEAD-2015-0136138		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Ill-defined disorder Insomnia		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2015	10783676	EXPEDITED (15-DAY)			US- GILEAD-2015-0136475	53 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Lacrimation increased Fatigue Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2015	10783682	EXPEDITED (15-DAY)			US- GILEAD-2015-0136431	57 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nervousness Fatigue Headache Insomnia		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2015	10783831	EXPEDITED (15-DAY)			US- GILEAD-2015-0136342	58 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia Back pain Flushing		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2015	10783832	EXPEDITED (15-DAY)			US- GILEAD-2015-0136347		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Influenza		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2015	10785721	DIRECT				51 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI 90-400MG GILEAD SCIENCES		S ORAL			GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2015	10785736	DIRECT				59 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache			HARVONI 90-400MG GILEAD SCIENCES	S ORAL	1 tab qd po		GILEAD	
Fatigue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2015	10785961	DIRECT		OT		58 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue			HARVONI 90-400MG GILEAD SCIENCES	S ORAL			GILEAD	
			LISINOPRIL	C				
			LEXAPRO	C				
			SPIROLACTONE	C				
			COREG	C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2015	10786089	DIRECT		HO		68 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Cardiac failure congestive			HARVONI 90/400MG GILEAD	S ORAL				
			ASPIRIN	C				
			BYSTOLIC	C				
			CETIRIZINE	C				
			CREON	C				
			LORAZEPAM	C				
			SYMBICORT	C				
			LASIX	C				
			POTASSIUM ELIXIR	C				



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2015	10746294	EXPEDITED (15-DAY)		OT	IE- GILEAD-2015-0133932	39 YR	Male	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Vomiting	HARVONI	S	ORAL	1 DF, QD		GILEAD
	RIBAVIRIN	S	ORAL	600 mg, BID		
	SEPTRIN	S	ORAL	960 mg, QD		
	SPIRONOLACTONE	C				
	RIFAXIMIN	C				
	THIAMINE	C				
	METHADONE	C				
	IRON	C				
	OMEPRAZOLE	C				
	LACTULOSE	C				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2015	10647567	EXPEDITED (15-DAY)			US- GILEAD-2014-0126535	56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Drug eruption	HARVONI	S	ORAL	1 DF, QD		GILEAD
Rash	LOSARTAN	C				
Headache	FLUTICASONE	C				
	PROAIR 00139502/	/	C			
	PRILOSEC 00661201/	/	C			
	FLUOXETINE	C				
	CARVEDILOL	C				
	IBUPROFEN	C				



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2015	10790312	EXPEDITED (15-DAY)			US- GILEAD-2015-0135670	52 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2015	10790513	EXPEDITED (15-DAY)			US- GILEAD-2015-0136688		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dizziness Ammonia increased Hypertension		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2015	10790654	EXPEDITED (15-DAY)			US- GILEAD-2015-0136105		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Joint injury		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2015	10790684	EXPEDITED (15-DAY)			US- GILEAD-2015-0136717		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sciatica		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2015	10790766	EXPEDITED (15-DAY)			US- GILEAD-2015-0136359	53 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Diarrhoea		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2015	10790969	EXPEDITED (15-DAY)		HO	US-GILEAD-2015-0136657		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Neck pain		HARVONI		S UNKNOW	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2015	10793493	DIRECT	Y	HO		52 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Upper respiratory tract infection		HARVONI 90/400MG GILEAD SCIENCES		S ORAL			GILEAD	
Confusional state Encephalopathy Hallucinations, mixed Pneumonia								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2015	10809141	DIRECT					Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Asthenia		HARVONI		S ORAL	1 Tablet QD PO		GILEAD	
		ASPIRIN		C				
		CLONAZEPAM		C				
		TAMSULOSIN		C				
		LOSARTAN/HET		C				
		FLUOXETINE		C				
		METOPROLOL		C				
Fatigue								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2015	10714885	EXPEDITED (15-DAY)		DE,OT	US- GILEAD-2015-0131279		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Death		HARVONI		S UNKNOWN	UNK		GILEAD	
Headache								
Overdose								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2015	10717597	EXPEDITED (15-DAY)		DE,OT	US- GILEAD-2015-0132178	61 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Myocardial infarction		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	
Haemoglobin decreased								
Respiratory disorder								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2015	10743028	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2015-0133022	68 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood creatinine increased		HARVONI		S UNKNOWN	UNK		GILEAD	
Dysphagia		CHLORPROMAZINE		C	UNK			
		DAPTOMYCIN		C	UNK			
		ERTAPENEM		C	UNK			
		FINASTERIDE		C	UNK			
		FLECAINIDE		C	UNK			
		MIDODRINE		C	UNK			
		RIFAXIMIN		C	UNK			
		VANCOMYCIN		C	UNK			



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2015	10793689	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0136683	74 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Blood alkaline phosphatase increased		HARVONI		S	UNKNOWN	UNK		GILEAD
Glomerular filtration rate decreased		ATORVASTATIN		C		UNK		
Alanine aminotransferase increased		LISINOPRIL		C				
Aspartate aminotransferase increased		HCTZ		C				
Blood bilirubin increased		OMEPRAZOLE		C				
		NICOTINE		C		UNK		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2015	10793696	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0136573		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Chest discomfort		HARVONI		S	UNKNOWN	UNK		GILEAD
Chills								
Confusional state								
Cyanosis								
Fatigue								
Hyperhidrosis								
Throat tightness								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2015	10794616	EXPEDITED (15-DAY)		DE,HO,OT	US- GILEAD-2015-0137345	59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Sudden death		HARVONI		S	UNKNOWN	UNK		GILEAD
Depression		LISINOPRIL		C	UNKNOWN	UNK		
Abdominal pain		LEXAPRO		C	UNKNOWN	UNK		
Diarrhoea								
Weight decreased								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2015	10794698	EXPEDITED (15-DAY)			US- GILEAD-2015-0136396		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hypoglycaemia		HARVONI		S UNKNOW	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2015	10794701	EXPEDITED (15-DAY)			US- GILEAD-2015-0136392	61 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2015	10812118	DIRECT	Y			56 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pain in extremity		HARVONI 90-400 MG		S ORAL	1 tablet		GILEAD	
Pain in extremity		ALBUTEROL		C				
Contusion		AMLODIPINE		C				
Fatigue		ASPIRIN		C				
		ATORVASTATIN		C				
		BUDESONIDE		C				
		CHOLECALCIFEROL		C				
		OMEPRAZOLE		C				
		SYMBICORT		C				
Decreased appetite								
Joint range of motion decreased								
Pain								
Peripheral swelling								



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2015	10717636	EXPEDITED (15-DAY)			US- GILEAD-2015-0131161		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood bilirubin increased		HARVONI RIBAVIRIN		S ORAL C ORAL	1 DF, QD 1200 mg, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2015	10783799	EXPEDITED (15-DAY)			US- GILEAD-2015-0136410		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Retching Headache Nausea		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2015	10798316	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0136497	63 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood pressure increased Epistaxis Tinnitus		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2015	10798332	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0137008	60 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hypertension		HARVONI		S UNKNOWN	UNK		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2015	10798336	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0137173	60 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pericarditis		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2015	10798366	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0137177	53 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pericarditis Dyspnoea		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2015	10798739	EXPEDITED (15-DAY)			US- GILEAD-2015-0136398	54 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Psychomotor hyperactivity Fatigue		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2015	10798754	EXPEDITED (15-DAY)		DE	IE- GILEAD-2015-0137044	41 YR	Female	IRL
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Malaise		HARVONI		S ORAL	1 DF, UNK		GILEAD	
		COPEGUS		C UNKNOWN	400 mg, BID			
		TRUVADA		C	UNK		GILEAD	
		ISENTRESS		C	400 mg, BID			
		PREZISTA		C	800 mg, QD			
		NORVIR		C	100 mg, QD			
		SEPTRIN		C	960 mg, QD			
		INDERAL		C	30 mg, BID			
		INDERAL		C				
		ALDACTONE 00006201/	/	C	75 mg, QD			
		TARGAXAN		C	550 mg, BID			
		PANTOPRAZOLE		C	20 mg, QD			
		LAXOSE		C	15 ml, TID			
		MIRTAZAPINE		C	30 mg, QD			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2015	10798757	EXPEDITED (15-DAY)			US- GILEAD-2015-0136696	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Accidental overdose		HARVONI		S UNKNOWN	UNK, BID		GILEAD	
		HARVONI		S UNKNOWN	UNK, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2015	10798759	EXPEDITED (15-DAY)			US- GILEAD-2015-0136715		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug level increased		HARVONI		S UNKNOWN			GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2015	10798893	EXPEDITED (15-DAY)			US- GILEAD-2015-0136908	43 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2015	10798908	EXPEDITED (15-DAY)			US- GILEAD-2015-0136952		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hepatitis C virus test positive		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2015	10798909	EXPEDITED (15-DAY)			US- GILEAD-2015-0137130		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S UNKNOWN	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2015	10798912	EXPEDITED (15-DAY)			US- GILEAD-2015-0136892	59 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2015	10798918	EXPEDITED (15-DAY)			US- GILEAD-2015-0136986		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Myalgia Back pain Musculoskeletal chest pain Musculoskeletal stiffness		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2015	10798932	EXPEDITED (15-DAY)			US- GILEAD-2015-0137306		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2015	10739242	EXPEDITED (15-DAY)			US- GILEAD-2015-0133205		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Viral test positive		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2015	10786032	EXPEDITED (15-DAY)		HO	US- GILEAD-2015-0136517	66 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Liver disorder		LETAIRIS		S UNKNOWN	10 mg, QD		GILEAD	
Malaise		LETAIRIS		S			GILEAD	
		HARVONI		S UNKNOWN			GILEAD	
		ADCIRCA		C				
		VANCOMYCIN		C				
		HYDROCODONE		C				
		AMBIEN		C				



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2015	10803144	EXPEDITED (15-DAY)		DE,HO,OT	DE- GILEAD-2015-0137543	66 YR	Male	DEU
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Cerebral haemorrhage		HARVONI		S ORAL	1 DF, QD		GILEAD	
		AGGRENEX		S ORAL	2 DF, QD			
		PREDNISOLONE		C ORAL	5 mg, QD			
		SANDIMMUN		C ORAL	25 mg, UNK			
		AZATHIOPRINE		C ORAL	50 mg, QD			
		DOCITON		C ORAL	10 mg, TID			
		PANTOZOL 01263204/	/	C ORAL	20 mg, QD			
		SPIRONOLACTONE A L		C ORAL	5 mg, QD			
		TORASEMID		C ORAL	10 mg, QD			
		TAMSULOSIN		C ORAL	0.4 mg, QD			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2015	10841344	DIRECT		OT		85 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Diarrhoea		HARVONI		S ORAL			GILEAD	
Muscle spasms								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2015	10853162	DIRECT	Y	OT		58 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dizziness		HARVONI		S ORAL	one tablet		GILEAD	
Visual impairment								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2015	10853183	DIRECT	Y			60 YR	Male	
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Peripheral coldness			HARVONI 90-400MG GILEAD SCIENCES	S ORAL			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2015	10853629	DIRECT		OT			Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Constipation			HAVONI	S ORAL			GILEAD	
			CODEINE	C				
			VICODIN	C				
			PROTONIX	C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2015	10853654	DIRECT	Y			59 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache			HARVONI 90-400MG GILEAD SCIENCES	S ORAL			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2015	10853655	DIRECT		OT		58 YR	Unknown	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug dose omission			HARVONI 90-400MG GILEAD SCIENCES	S ORAL			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2015	10854826	DIRECT		HO		57 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Hepatic encephalopathy		HARVONI		S	ORAL			GILEAD
Frequent bowel movements		LEXAPRO		C				
		FUROSEMIDE ORAL		C				
		LACTULOSE		C				
		NADOLOL		C				
		NEOMYCIN		C				
		PROMETHAZINE		C				
		RIFAXIMIN		C				
		SPIRONOLACTONE		C				
Anaemia								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2015	10854847	DIRECT				53 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Headache		HARVONI 90-400MG GILEAD SCIENCES		S	ORAL			GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2015	10860992	DIRECT	Y			44 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Influenza like illness		HARVONI 90-400MG TAB GILEAD SCIENCES		S	ORAL			GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2015	10860998	DIRECT	Y			60 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Fluid imbalance		HARVONI		S	ORAL	1		GILEAD



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2015	10861001	DIRECT	Y			65 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue Nausea		HARVONI 90-400 MG		S ORAL	one tablet		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2015	10861094	DIRECT	Y				Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue Cough Sleep disorder		HARVONI		S ORAL	1 pill, QD, Oral	4 WEEK		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2015	10861175	DIRECT	Y	HO,LT		68 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Atrial fibrillation		HARVONI		S ORAL	1			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10691200	EXPEDITED (15-DAY)			US- GILEAD-2014-0128242		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dyspepsia		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10737992	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0133092	63 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Orthostatic hypotension		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10739122	EXPEDITED (15-DAY)			US- GILEAD-2015-0132713	53 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Renal disorder Back pain Muscle strain		HARVONI		S ORAL	1 UNK, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10756393	EXPEDITED (15-DAY)			US- GILEAD-2015-0133956	61 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Alpha 1 foetoprotein decreased		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10798907	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0137063		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Viral load increased Drug ineffective		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10830645	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0131947	62 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pancytopenia Glomerular filtration rate abnormal		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10833299	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0137835		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rheumatoid arthritis		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10833571	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2015-0136100		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Multiple fractures Road traffic accident		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10836026	EXPEDITED (15-DAY)			US- GILEAD-2015-0137107	55 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Overdose		HARVONI HARVONI		S ORAL S ORAL	1 DF, BID 1 DF, QD		GILEAD GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10836028	EXPEDITED (15-DAY)			US- GILEAD-2015-0137109	51 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Anxiety Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10836029	EXPEDITED (15-DAY)			US- GILEAD-2015-0137007		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug dose omission		HARVONI		S UNKNOWN			GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10836036	EXPEDITED (15-DAY)			US- GILEAD-2015-0137110	66 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Tinnitus		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10836061	EXPEDITED (15-DAY)			US- GILEAD-2015-0137270	57 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Anxiety Nausea		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10862796	DIRECT	Y	HO		39 YR	Male	
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hypertension Tachycardia		HARVONI		S ORAL			UNKNOWN	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10862821	DIRECT	Y			56 YR	Female	
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Palpitations Chest discomfort		HARVONI		S ORAL	1 tablet		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10862894	DIRECT	Y			58 YR	Male	
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Thirst		HARVONI 90/400 MG GILEAD		S ORAL			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10866431	DIRECT		HO		63 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Mental status changes Convulsion		HARVONI		S ORAL	1 pill QD Oral		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2015	10866437	DIRECT		HO		67 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Gastric disorder Clostridium difficile infection		HARVONI		S ORAL	1 QD Oral		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10712072	EXPEDITED (15-DAY)			US- GILEAD-2015-0130952	48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10712097	EXPEDITED (15-DAY)			US- GILEAD-2015-0131130		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Influenza like illness Pyrexia		HARVONI		S UNKNOWN			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10717661	EXPEDITED (15-DAY)			US- GILEAD-2015-0131188	58 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Genital herpes Abasia Back pain Lymphadenopathy Muscle spasms Nasopharyngitis Pain in extremity		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10739143	EXPEDITED (15-DAY)			US- GILEAD-2015-0133372	45 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Feeling hot Irritability Diarrhoea Headache		HARVONI NEXIUM 01479302/ ALEVE	/	S ORAL C ORAL C ORAL	1 DF, QD 20 mg, UNK 2 DF, prn		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10777032	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0135860	24 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dermatitis bullous Rash Rash erythematous		HARVONI		S UNKNOWN	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10780827	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0130428		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective		HARVONI		S ORAL	1 DF, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10844737	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0137324		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Renal impairment Blood glucose increased		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10844809	EXPEDITED (15-DAY)		DE,OT	US- GILEAD-2015-0138178		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Death		HARVONI RIBAVIRIN		S UNKNOWN C			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10846534	EXPEDITED (15-DAY)			US- GILEAD-2015-0137187		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Alopecia		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10846600	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2015-0138134	55 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chronic hepatic failure		HARVONI		S UNKNOWN			GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10846602	EXPEDITED (15-DAY)			US- GILEAD-2015-0137255	60 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10846607	EXPEDITED (15-DAY)			US- GILEAD-2015-0137271	64 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea Fatigue Insomnia		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10846626	EXPEDITED (15-DAY)			US- GILEAD-2015-0137275	56 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Myalgia		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10846678	EXPEDITED (15-DAY)			US- GILEAD-2015-0137287	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10846681	EXPEDITED (15-DAY)			US- GILEAD-2015-0137362		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Accidental overdose		HARVONI		S ORAL	1 DF, BID		GILEAD	
		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847206	EXPEDITED (15-DAY)			US- GILEAD-2015-0137394		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pruritus		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847217	EXPEDITED (15-DAY)			US- GILEAD-2015-0137582		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Accidental overdose		HARVONI		S UNKNOWN	UNK		GILEAD	
		HARVONI		S UNKNOWN	2 UNK, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847223	EXPEDITED (15-DAY)			US- GILEAD-2015-0137552	63 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Vomiting		HARVONI		S ORAL	df		GILEAD	
Diarrhoea								
Dizziness postural								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847226	EXPEDITED (15-DAY)			US- GILEAD-2015-0137840		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Gastroesophageal reflux disease Dyspepsia		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847227	EXPEDITED (15-DAY)			US- GILEAD-2015-0137446	55 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue Dyspepsia Headache		HARVONI		S ORAL	1 DF, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847241	EXPEDITED (15-DAY)			US- GILEAD-2015-0137587	54 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Diarrhoea		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847245	EXPEDITED (15-DAY)			US- GILEAD-2015-0137592	55 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Anxiety		HARVONI CHANTIX		S ORAL S UNKNOWN	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847247	EXPEDITED (15-DAY)			US- GILEAD-2015-0137848	65 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Anxiety		HARVONI		S UNKNOWN	UNK		GILEAD	
		INSULIN		C				
		COLACE		C				
		VASOTEC 00574902/	/	C				
		METHADONE		C				
		LASIX	/00032601/	C				
		ALDACTONE 00006201/	/	C				
		LACTULOSE		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847251	EXPEDITED (15-DAY)			US- GILEAD-2015-0137448	55 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Urticaria		HARVONI		S UNKNOWN	UNK		GILEAD	
Rash		HYDROXYCHLOROQUINE		S UNKNOWN	UNK			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847256	EXPEDITED (15-DAY)			US- GILEAD-2015-0137504	54 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
Fatigue								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847259	EXPEDITED (15-DAY)			US- GILEAD-2015-0137546		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Aspartate aminotransferase increased		HARVONI		S UNKNOWN	UNK		GILEAD	
Alanine aminotransferase increased		LIPITOR		S UNKNOWN	UNK			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847272	EXPEDITED (15-DAY)			US- GILEAD-2015-0137943	61 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847305	EXPEDITED (15-DAY)			US- GILEAD-2015-0137846	67 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Anxiety		HARVONI		S UNKNOWN	UNK		GILEAD	
		PROPANOLOL 00030001/		/ C				
		LACTULOSE		C				
		VENTOLIN 00139501/		/ C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847312	EXPEDITED (15-DAY)			US- GILEAD-2015-0137953	60 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847369	EXPEDITED (15-DAY)			US- GILEAD-2015-0137965	55 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Abdominal distension Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847461	EXPEDITED (15-DAY)			US- GILEAD-2015-0137451	53 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S UNKNOWN	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847512	EXPEDITED (15-DAY)			US- GILEAD-2015-0137678		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Road traffic accident Drug abuse		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847516	EXPEDITED (15-DAY)			US- GILEAD-2015-0137558	50 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nasopharyngitis		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847529	EXPEDITED (15-DAY)			US- GILEAD-2015-0137888	61 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Skin lesion		HARVONI		S UNKNOWN	UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847575	EXPEDITED (15-DAY)		LT,OT	DE- GILEAD-2015-0138413	59 YR	Male	DEU
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pulmonary fibrosis		HARVONI		S ORAL	1 DF, QD		GILEAD	
Condition aggravated		ACC /00082801/		C ORAL	600 mg, TID			
Respiratory failure		THYRONAJOD		C ORAL	50 µg, QD			
		PREDNISOLON /		C ORAL	UNK			
		00016201/						
		TORASEMID		C ORAL	5 mg, UNK			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847665	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0137143		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Unevaluable event		HARVONI		S UNKNOWN			GILEAD	
Weight decreased								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847696	EXPEDITED (15-DAY)			US- GILEAD-2015-0137977		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood creatine phosphokinase increased		HARVONI		S ORAL			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10847706	EXPEDITED (15-DAY)			US- GILEAD-2015-0138026	40 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dyspepsia		HARVONI		S UNKNOWN			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2015	10868470	DIRECT				63 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea		HARVONI		S ORAL	90-400 mg		GILEAD	
		FLUTICASONE		C				
		LEVITRA		C				
Headache								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2015	10855487	EXPEDITED (15-DAY)			US- GILEAD-2015-0136972		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Accidental overdose		HARVONI		S UNKNOWN	2 DF, UNK		GILEAD	
		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2015	10856268	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0138007		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Bladder cancer		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2015	10856385	EXPEDITED (15-DAY)		HO,OT	GB- GILEAD-2015-0137748		Male	GBR
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hepatic cirrhosis		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2015	10856443	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0138540		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Cryoglobulinaemia Burning sensation Erythema Pruritus Rash		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2015	10856496	EXPEDITED (15-DAY)			US- GILEAD-2015-0137478	46 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2015	10856512	EXPEDITED (15-DAY)			US- GILEAD-2015-0137877	60 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Feeling cold Peripheral coldness		HARVONI LEVOTHYROXINE TRAZODONE BUPROPION		S ORAL C C C	1 DF, QD 100 µg, QD 100 mg, UNK 100 mg, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2015	10856575	EXPEDITED (15-DAY)			US- GILEAD-2015-0138048	58 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2015	10856603	EXPEDITED (15-DAY)			US- GILEAD-2015-0138120	48 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sinusitis		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2015	10856662	EXPEDITED (15-DAY)			US- GILEAD-2015-0138130	43 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nasopharyngitis		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2015	10856686	EXPEDITED (15-DAY)			US- GILEAD-2015-0138444		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Negative thoughts		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2015	10856691	EXPEDITED (15-DAY)			US- GILEAD-2015-0138537		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2015	10856709	EXPEDITED (15-DAY)			US- GILEAD-2015-0138532		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Dizziness		HARVONI		S UNKNOWN			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2015	10856718	EXPEDITED (15-DAY)			US- GILEAD-2015-0138582		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Metabolic acidosis Hyperkalaemia		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2015	10856773	EXPEDITED (15-DAY)			US- GILEAD-2015-0138639		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Abdominal pain upper		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2015	10863418	EXPEDITED (15-DAY)			US- GILEAD-2015-0138545		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2015	10871523	DIRECT		OT		59 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug dose omission		HARVONI 90/400MG GILEAD		S ORAL			GILEAD	
		METOPROLOL		C				
		LISINOPRIL		C				
		HYDROCODONE/APAP		C				
		ASA		C				
		ACCU-CHEK AVIVA PLUS		C				



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2015	10739296	EXPEDITED (15-DAY)			US- GILEAD-2015-0133446	36 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S UNKNOWN	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2015	10752207	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0134070	62 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Diverticulitis		HARVONI		S UNKNOWN	UNK		GILEAD	
Rash generalised		PRAVASTATIN		C	20 mg, UNK			
		COUMADIN /		C				
		00014802/						
		GLIPIZIDE		C				
		LEVEMIR		C				
		LISINOPRIL		C				
		GABAPENTIN		C				
		AMBIEN		C				
		AMITRIPTYLINE		C				
		NORCO		C	UNK, prn			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2015	10798483	EXPEDITED (15-DAY)		DE,HO,OT	AT- GILEAD-2015-0137032	54 YR	Male	AUT
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Septic shock		HARVONI		S ORAL	1 DF, UNK		GILEAD	
Enterocolitis		SPIRONOLACTONE		C ORAL	50 mg, UNK			
Abdominal pain								
General physical health deterioration								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2015	10863535	EXPEDITED (15-DAY)			US- GILEAD-2015-0137962	47 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood creatinine increased		HARVONI		S UNKNOWN	UNK		GILEAD	
		LEVOTHYROXINE		C				
		BUPROPION		C				
		INDOMETHACIN 00003801/		/ C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2015	10863593	EXPEDITED (15-DAY)			US- GILEAD-2015-0138067		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Vomiting		HARVONI		S UNKNOWN			GILEAD	
Nausea		RIBAVIRIN		S UNKNOWN				
Diarrhoea		FIORICET		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2015	10863603	EXPEDITED (15-DAY)			US- GILEAD-2015-0137844	64 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S UNKNOWN			GILEAD	
Amnesia								
Malaise								
Tremor								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2015	10863605	EXPEDITED (15-DAY)			US- GILEAD-2015-0137983		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Vertigo		HARVONI		S UNKNOWN	UNK		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2015	10863630	EXPEDITED (15-DAY)			US- GILEAD-2015-0138055		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Enzyme level decreased		HARVONI		S UNKNOWN			GILEAD	
Platelet disorder		RIBAVIRIN		S UNKNOWN	UNK			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2015	10863660	EXPEDITED (15-DAY)			US- GILEAD-2015-0138138		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Thermal burn		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2015	10864251	EXPEDITED (15-DAY)			US- GILEAD-2015-0139019	63 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea		HARVONI		S ORAL	1 DF, QD		GILEAD	
Headache								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2015	10864253	EXPEDITED (15-DAY)			US- GILEAD-2015-0139018	60 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2015	10879531	DIRECT		OT		65 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI 90-400MG GILEAD SCIENCES		S ORAL	1 tablet Daily Oral		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2015	10879854	DIRECT				53 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Menstrual disorder		HARVONI 90-400MG GILEAD SCIENCES		S ORAL			GILEAD	
		NYSTATIN		C				
		GAVILYTE-G		C				
		METFORMIN		C				
		VIT C		C				
		CORRECTOL		C				
		MULTIVITAL		C				
		ENALAPRIL		C				
		HCTZ/TRAIMT		C				
		LORAZEPAM		C				
Menstrual disorder								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2015	10879939	DIRECT				63 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
		HARVONI 90-400MG GILEAD SCIENCES		S ORAL			GILEAD	
Diarrhoea		WARFRAIN		C				
Rash		PATANOL		C				
Rash		FENOFIBRATE		C				
		CEREFOLIN		C				
		RISPERDAL		C				
Migraine								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2015	10777354	EXPEDITED (15-DAY)		HO	US-GILEAD-2015-0135806	45 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Throat tightness		HARVONI		S UNKNOWN	UNK		GILEAD	
Rash generalised		SYNTHROID		C	UNK			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2015	10867007	NON-EXPEDITED			US-PFIZER INC-2015070354	55 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Anxiety		Chantix		S	UNK		PFIZER	
		HARVONI		S ORAL	1 DF, 1x/day			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2015	10867579	EXPEDITED (15-DAY)			US-GILEAD-2015-0138553	57 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Myalgia		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2015	10868079	EXPEDITED (15-DAY)			US-GILEAD-2015-0138155	44 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Influenza like illness		HARVONI		S ORAL	1 DF, QD		GILEAD	
Headache								
Insomnia								
Myalgia								
Nausea								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2015	10868601	EXPEDITED (15-DAY)			US- GILEAD-2015-0139153	25 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pain Fatigue Headache Myalgia		HARVONI		S ORAL	1 Unknown, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2015	10868801	EXPEDITED (15-DAY)			US- GILEAD-2015-0139146	54 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pruritus Abdominal discomfort Diarrhoea Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2015	10877709	DIRECT				61 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pain in extremity Hypoaesthesia		HARVONI OMEPRAZOLE CYCLOSPORINE AMLODIPINE MAGNESIUM		S ORAL C C C C			GILEAD	
Pain in extremity Sensory disturbance								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2015	10877973	DIRECT		OT		58 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Decreased appetite		RIBAVIRIN		S	ORAL			ZYDUS PHARM
Nausea		METHADONE		C				
Insomnia		HUMALOG INSULIN		C				
		SYNTHROID		C				
		CEPHALEXIN		C				
		LISINOPRIL		C				
		ATENOLOL		C				
		AMLODIPINE		C				
		LEVOTHYROXINE		C				
		FUROSEMIDE		C				
		POTASSIUM		C				
		A & D		C				
		RIBAVIRIN		C				
		CLONIDINE		C				
		MAGNESIUM		C				
		VIT D		C				
Abdominal pain upper								
Fatigue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2015	10880894	DIRECT				64 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Abdominal pain upper		HARVONI 90/400 MG GILEAD		S	ORAL			GILEAD



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2015	10881494	DIRECT	Y			59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Diarrhoea Flatulence		HARVONI 90/400 MG GILEAD		S ORAL	one tablet		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2015	10882614	DIRECT		HO,DS		61 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Cluster headache Diplopia Migraine		HARVONI		S	1 pill am mouth		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2015	10714690	EXPEDITED (15-DAY)		DE,OT	CA- GILEAD-2015-0131927	60 YR	Male	CAN
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Haemorrhage		HARVONI		S ORAL	1 DF, UNK		GILEAD	
		RIBAVIRIN		C ORAL	400 mg, UNK			
		PANGRAF		C ORAL	1 mg, UNK			
		RANITIDINE		C ORAL	150 mg, UNK			



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2015	10870213	EXPEDITED (15-DAY)		HO	FR-SA-2015SA022121	14 YR	Male	FRA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Epilepsy		DEPAKINE		S ORAL				
		DEPAKINE		S ORAL				
		LASILIX		S ORAL				
		IMOVANE		S ORAL				
		PANTOPRAZOLE		S ORAL				
		HARVONI		S ORAL				
		XEROQUEL		S ORAL				
		ATARAX		S ORAL	strenght: 25 mg			
		ADCIRCA		S ORAL				
		COVERSYL		S ORAL				
		ALDACTONE		S ORAL				
		NICOBION		S ORAL				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2015	10870716	EXPEDITED (15-DAY)			US-GILEAD-2015-0139185	63 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Diarrhoea		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2015	10870725	EXPEDITED (15-DAY)			US-GILEAD-2015-0139299		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Peripheral swelling		HARVONI		S UNKNOWN			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2015	10870752	EXPEDITED (15-DAY)			US- GILEAD-2015-0139205	60 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea Diarrhoea		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2015	10872112	EXPEDITED (15-DAY)			US- GILEAD-2015-0138122		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Insomnia		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2015	10872210	EXPEDITED (15-DAY)			US- GILEAD-2015-0138580	46 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash Abdominal discomfort		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2015	10872222	EXPEDITED (15-DAY)			US- GILEAD-2015-0139411	63 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2015	10872229	EXPEDITED (15-DAY)			US- GILEAD-2015-0139393	62 YR	Unknown	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Psychomotor hyperactivity Cyst drainage Pain in extremity Pruritus		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2015	10872241	EXPEDITED (15-DAY)			US- GILEAD-2015-0138742	56 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nasopharyngitis		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2015	10872260	EXPEDITED (15-DAY)			US- GILEAD-2015-0138745		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hepatic pain		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2015	10872280	EXPEDITED (15-DAY)			US- GILEAD-2015-0138609	64 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2015	10872281	EXPEDITED (15-DAY)			US- GILEAD-2015-0138610	64 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Lethargy Fatigue Feeling abnormal		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2015	10872282	EXPEDITED (15-DAY)			US- GILEAD-2015-0138641		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Alopecia universalis		HARVONI		S UNKNOWN			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
27-Feb-2015	10735713	EXPEDITED (15-DAY)		HO	IE-ROCHE-1525375	61 YR	Male	IRL	
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>		<u>Dosage Text</u>		<u>Duration</u>	<u>Manufacturer</u>
Haemoglobin decreased		Copegus		S UNKNOWN		400mg mane and 600mg tarde			
Blood phosphorus decreased		HARVONI		S ORAL		400mg/ 90mg Most recent therapy prior to the event was received on 09/Jan/2015			
Blood potassium decreased		TRUVADA		C UNKNOWN		245mg/200mg			
		PREZISTA		C UNKNOWN					
		NORVIR		C UNKNOWN					
		LANSOPRAZOLE		C UNKNOWN					
		SEPTRIN FORTE		C UNKNOWN		160mg/800mg Tablets			
		METHADONE		C UNKNOWN					
		LAXOSE		C UNKNOWN					
		FUROSEMIDE		C UNKNOWN		Mane			
		Diazepam		C UNKNOWN					
		THIAMINE		C UNKNOWN					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
27-Feb-2015	10746444	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0133704		Male	USA	
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>		<u>Dosage Text</u>		<u>Duration</u>	<u>Manufacturer</u>
Hepatitis C		HARVONI		S ORAL		1 DF, QD			GILEAD
Drug ineffective		NORVASC		C					
		AMARYL		C					



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10783648	EXPEDITED (15-DAY)		HO,OT	IE- GILEAD-2015-0136051	51 YR	Male	IRL
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Sepsis		HARVONI		S	ORAL	1 DF, QD		GILEAD
Syncope		RIBAVIRIN		S	ORAL	UNK		
Body temperature decreased		ALDACTONE 00006201/		/	C			
		THIAMINE			C			
		PARACETAMOL			C			
		RIFAXIMIN			C			
		OMEPRAZOLE			C			
		PROPRANOLOL			C			
		LACTULOSE			C			
		MOVICOL 01749801/		/	C			
		CIPROFLOXACIN			C			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10872038	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0138727	62 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Alanine aminotransferase increased		HARVONI		S	UNKNOWN	UNK		GILEAD
Aspartate aminotransferase increased								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10873696	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0138602		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Gastric bypass		HARVONI		S	UNKNOWN	UNK		GILEAD
Hepatitis C virus test positive								
Wrong technique in drug usage process								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10874140	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0138604		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Lipase increased Abdominal pain Amylase increased Dyspnoea Malaise		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10874158	EXPEDITED (15-DAY)			US- GILEAD-2015-0138606	57 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Irritability Insomnia		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10874166	EXPEDITED (15-DAY)			US- GILEAD-2015-0138904		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Feeling hot Rash		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10874168	EXPEDITED (15-DAY)			US- GILEAD-2015-0138608	59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10874169	EXPEDITED (15-DAY)			US- GILEAD-2015-0138936	61 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Anxiety Fatigue Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10874180	EXPEDITED (15-DAY)			US- GILEAD-2015-0139170	64 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nasopharyngitis Pyrexia		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10874189	EXPEDITED (15-DAY)			US- GILEAD-2015-0139216	61 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10874222	EXPEDITED (15-DAY)		HO	FR- ABBVIE-15P-056-135327 8-00	14 YR	Male	FRA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Epilepsy		DEPAKINE		S ORAL				
Brain death		LASILIX		S ORAL				
		IMOVANE		S ORAL				
		PANTOPRAZOLE		S ORAL				
		HARVONI (LEDIPASVIR/ SOFOSBUVIR)		S ORAL				
		XEROQUEL		S ORAL				
		ATARAX		S ORAL				
		ADCIRCA		S ORAL				
		COVERSYL		S ORAL				
		ALDACTONE		S ORAL				
		NICOTINAMIDE		S ORAL				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10874237	EXPEDITED (15-DAY)			US- GILEAD-2015-0139440	54 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nasopharyngitis		HARVONI		S ORAL	1 DF, QD		GILEAD	
Fatigue								
Nausea								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10874264	EXPEDITED (15-DAY)			US- GILEAD-2015-0139803	30 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash pruritic		HARVONI		S UNKNOWN	UNK		GILEAD	
Rash		RAMIPRIL		C				



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10874283	EXPEDITED (15-DAY)			US- GILEAD-2015-0139681	67 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chest pain		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10875065	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0138711	60 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hepatitis C Drug ineffective		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10875372	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0139346		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Crohn's disease		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10881925	DIRECT				55 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S ORAL	90mg/400mg 1qd po		GILEAD	
Nausea		VICTOZA		C				
Insomnia		LISINOPRIL		C				
Vision blurred		PERCOCET		C				
		ATIVAN		C				
Diarrhoea								
Diplopia								
Headache								
Lymphadenopathy								
Vomiting								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10884742	DIRECT					Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue			HARVONI 90MG-400MG	S ORAL			GILEAD	
			MORPHINE SULFATE	C				
			CYCLOBENZAPRINE	C				
			FLUVIRIN	C				
			CITALOPRAM	C				
			GLUCOS/CHOND	C				
			MORPHINE SULF	C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10886566	DIRECT					Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue			HARVONI	S ORAL			GILEAD	
			MORPHINE SULFATE	C				
			CYCLOBENZAPRINE	C				
			FLUVIRIN	C				
			CITALOPRAM	C				
			GLUCOS/CHOND D/S	C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2015	10691719	EXPEDITED (15-DAY)			US- GILEAD-2014-0129934	44 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Anxiety			HARVONI	S ORAL	1 DF, QD		GILEAD	
Abdominal discomfort								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2015	10722362	EXPEDITED (15-DAY)			US- GILEAD-2015-0131890	23 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Pregnancy	HARVONI	S	UNKNOWN			GILEAD

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2015	10727419	EXPEDITED (15-DAY)		HO	IE- GILEAD-2015-0132636	38 YR	Female	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Haemoglobin decreased	HARVONI	S	ORAL	1 DF, QD		GILEAD
	COPEGUS	S	ORAL	1000 mg, QD		
	COPEGUS	S	ORAL	400 mg, BID		
	TRUVADA	C		1 DF, UNK		GILEAD
	DAPSONE	C		100 mg, QD		
	LANSOPRAZOLE	C		15 mg, UNK		
	ZITHROMAX	C		1.25 g, Q1Wk		
	PREZISTA	C		800 mg, QD		
	LAXOSE	C		15 ml, TID		
	INDERAL	C		10 mg, BID		
NORVIR	C		100 mg, QD			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2015	10739119	EXPEDITED (15-DAY)			US- GILEAD-2015-0132783	54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Flatulence Abdominal distension Abdominal pain	HARVONI	S	UNKNOWN	UNK		GILEAD



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2015	10739308	EXPEDITED (15-DAY)			US- GILEAD-2015-0133814	64 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Influenza Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2015	10746259	EXPEDITED (15-DAY)		HO	IE- GILEAD-2015-0133931	61 YR	Male	IRL
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Haemoglobin decreased		HARVONI		S ORAL	1 DF, UNK		GILEAD	
Blood phosphorus decreased		COPEGUS		S UNKNOWN	400 mg in the morning and 600 mg in the evening, UNK		GILEAD	
Blood potassium decreased		TRUVADA		C	1 DF, UNK		GILEAD	
		TRUVADA		C			GILEAD	
		PREZISTA		C	800 mg, QD			
		NORVIR		C	100 mg, QD			
		LANSOPRAZOLE		C	15 mg, QD			
		SEPTRIN		C	960 mg, QD			
		METHADONE		C	40 mg, QD			
		LAXOSE		C	15 ml, BID			
		FUROSEMIDE		C	40 mg, QD			
		DIAZEPAM		C	2 mg, QD			
		THIAMINE		C	300 mg, QD			



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2015	10749337	EXPEDITED (15-DAY)		OT	IE- GILEAD-2015-0133933	58 YR	Female	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Renal impairment	HARVONI	S	ORAL	1 DF, QD		GILEAD
	RIBAVIRIN	S	ORAL	200 mg, BID		
	PROGRAF	S	ORAL	1 mg, BID		
	PROGRAF	S	ORAL	1 mg, QD		
	COVERSYL ARGININE	S	ORAL	2.5 mg, QD		
	CO-TRIMOXAZOLE	C				
	URSOFALK	C		250 mg, UNK		
	HALCION	C				
	OMEPRAZOLE	C				
	RIFAXIMIN	C				
	TRANEXAMIC ACID	C				
	CARVEDILOL	C				
	VENLAFAXINE	C				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2015	10749348	EXPEDITED (15-DAY)		OT	IE- GILEAD-2015-0133934	51 YR	Male	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Lower respiratory tract infection	HARVONI	S	ORAL	400mg/90mg		GILEAD
	RIBAVIRIN	S	ORAL	UNK		
	SPIRONOLACTONE	C				
	THIAMINE	C				
	RIFAXIMIN	C				
	OMEPRAZOLE	C				
	PROPANOLOL 00030001/	/	C			
	CIPROFLOXACIN	C				



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2015	10879614	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0139306		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Liver transplant		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2015	10880004	EXPEDITED (15-DAY)			US- GILEAD-2015-0139186		Unknown	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Myalgia		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2015	10880005	EXPEDITED (15-DAY)			US- GILEAD-2015-0139194	34 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Irritability Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2015	10880305	EXPEDITED (15-DAY)		DE	US- GILEAD-2015-0140087		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Bleeding varicose vein		HARVONI		S UNKNOWN			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2015	10897211	DIRECT	Y			54 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Dyspnoea		HARVONI		S	ORAL	1 pill QD		GILEAD
Nervous system disorder		SYNTHROID		S				
		KYLETRA		C				
		INVIRASE		C				
		ISENTRESS		C				
		VALTREX		C				
Drug interaction								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2015	10897574	DIRECT				63 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Fatigue		HARVONI 90-400MG TAB GILEAD SCIENCES		S	ORAL			GILEAD
		ZOLPIDEM		C				
		LOSARTAN		C				
		AMLODIPINE		C				
		LIDOCAIN		C				
		OXYCONTIN		C				
		CRESTOR		C				
		CLONIDINE		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2015	10897841	DIRECT	Y			56 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Headache		HARVONI		S	ORAL	one tablet		GILEAD
Fatigue								
Fungal infection								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2015	10898169	DIRECT	Y			56 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Abdominal discomfort Insomnia Irritability		HARVONI		S	ORAL			GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10741222	EXPEDITED (15-DAY)			US- GILEAD-2015-0133671		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Dysphagia Intentional product misuse		HARVONI		S	ORAL	UNK		GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10756417	EXPEDITED (15-DAY)		OT	IE- GILEAD-2015-0134406	57 YR	Male	IRL
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Encephalopathy Peritonitis bacterial		HARVONI		S	ORAL	1 DF, QD		GILEAD
		RIBAVIRIN		S	ORAL	600 mg, BID		
		OMEPRAZOLE			C			
		PROPANOLOL 00030001/		/	C			
		CIPROFLOXACIN			C			
		SPIRONOLACTONE			C			
		RIFAXIMIN			C			



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10847525	EXPEDITED (15-DAY)			US- GILEAD-2015-0137883		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pyrexia Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10856664	EXPEDITED (15-DAY)			US- GILEAD-2015-0138125	58 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Vision blurred Anxiety Headache Nausea		HARVONI		S ORAL	1 UNK, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10861413	EXPEDITED (15-DAY)		DE,HO	DE-B.I. PHARMACEUTICALS,IN C./RIDGEFIELD-2015- BI-08361BP	66 YR	Male	DEU
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Cerebral haemorrhage		AGGRENOX HARVONI PREDNISOLONE SANDIMMUN AZATHIOPRINE DOCITON PANTOZOL SPIRONOLACTONE A L TORASEMID TAMSULOSIN		S ORAL S ORAL C UNKNOWN C UNKNOWN C UNKNOWN C UNKNOWN C UNKNOWN C UNKNOWN C UNKNOWN C UNKNOWN	2 anz 1 anz		BOEHRINGER INGELHEIM	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10875360	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0139065		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood pressure increased		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10882131	EXPEDITED (15-DAY)			US-GILEAD-2015-0139116		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Malaise Fatigue		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10882246	EXPEDITED (15-DAY)			US-GILEAD-2015-0139931	60 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Constipation		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10882274	EXPEDITED (15-DAY)			US-GILEAD-2015-0139975	59 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Sleep disorder		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10882434	EXPEDITED (15-DAY)			US-GILEAD-2015-0139987	67 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Overdose		HARVONI		S ORAL	UNK Unknown, BID		GILEAD	
		HARVONI		S ORAL	UNK Unknown, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10882748	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0139174		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pneumonia		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10883115	EXPEDITED (15-DAY)			US- GILEAD-2015-0138985	58 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea Vomiting		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10883124	EXPEDITED (15-DAY)			US- GILEAD-2015-0138975	68 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Labyrinthitis Ear disorder		HARVONI		S ORAL	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10883444	EXPEDITED (15-DAY)			US- GILEAD-2015-0140241	59 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10883474	EXPEDITED (15-DAY)			US- GILEAD-2015-0140323	64 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10883506	EXPEDITED (15-DAY)			US- GILEAD-2015-0138581		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug interaction		HARVONI		S UNKNOWN			GILEAD	
Feeling abnormal		RITONAVIR		S UNKNOWN				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10883589	EXPEDITED (15-DAY)			US- GILEAD-2015-0139295		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dyspepsia		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10883618	EXPEDITED (15-DAY)			US- GILEAD-2015-0139479		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10900528	DIRECT		OT		63 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S ORAL			GILEAD	
Constipation		STOOL SOFTNER CAP		C				
		LISINOPRIL		C				
		HYDROCHLOROT		C				
		OMEPRAZOLE		C				
		PROZAC		C				
		MULTI VITAMIN		C				
Headache								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10900551	DIRECT				62 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI 90-400MG GILEAD SCIENCES		S ORAL			GILEAD	
Weight decreased		NORTIPTYLINE		C				
Headache								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10900616	DIRECT	Y			59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 tablet		GILEAD	
Myalgia								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10900617	DIRECT	Y			56 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
International normalised ratio decreased		HARVONI		S ORAL	1 tablet, daily, po		GILEAD	
Product substitution issue								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10900910	DIRECT	Y	LT		68 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Oropharyngeal cancer		HARVONI 90/400 MG GILEAD		S	ORAL	1 dose		GILEAD
		WARFARIN		C				
		CALCIUM		C				
		CHOLECALCIFEROL		C				
		HYDROCODONE		C				
		SUMATRIPTONE		C				
		DILTIAZEM		C				
		TESTOSTERONE		C				
		SIROLIMUS		C				
		TEMAZEPAM		C				
		MAGNESIUM		C				
Recurrent cancer								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2015	10901069	DIRECT				69 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Confusional state		HARVONI		S	ORAL	one tablet qd oral		
Dysgraphia								
Feeling jittery								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10627293	EXPEDITED (15-DAY)			US- GILEAD-2014-0125062	60 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Rash		HARVONI		S	UNKNOWN	90 mg, UNK		GILEAD



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10752225	EXPEDITED (15-DAY)		HO	IE- GILEAD-2015-0134164	56 YR	Male	IRL
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Bleeding varicose vein		HARVONI		S ORAL	1 DF, UNK		GILEAD	
		COPEGUS		S UNKNOWN	600 mg, BID			
		TRUVADA		C			GILEAD	
		ISENTRESS		C	400 mg, BID			
		OMEPRAZOLE		C	20 mg, QD			
		FUROSEMIDE		C	40 mg, QD			
		ALDACTONE 00006201/	/	C	100 mg, QD			
		INDERAL		C	10 mg, BID			
		DIAZEPAM		C	5 mg, UNK			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10771921	EXPEDITED (15-DAY)		DE,HO	US- GILEAD-2015-0135884		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Overdose		HARVONI		S UNKNOWN	1 DF, UNK		GILEAD	
		VICODIN		S UNKNOWN				



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10861433	EXPEDITED (15-DAY)		DE,HO,OT	DE-B.I. PHARMACEUTICALS,IN C./RIDGEFIELD-2015- BI-08148DE	66 YR	Male	DEU
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Cerebral haemorrhage		AGGRENEX		S ORAL	2 anz		BOEHRINGER INGELHEIM	
		HARVONI		S ORAL	1 anz			
		PREDNISOLON		C ORAL	5 mg			
		SANDIMMUN		C ORAL	125 mg			
		AZATHIOPRIN		C UNKNOWN	50 mg			
		DOCITON		C ORAL	30 mg			
		PANTOZOL		C ORAL	20 mg			
		SPIRONOLACTON AL		C ORAL	0.5 anz			
		TORASEMID		C ORAL	10 mg			
		TAMSULOSIN		C ORAL	0.4 mg			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10883428	EXPEDITED (15-DAY)			US- GILEAD-2015-0140065	64 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Back pain		HARVONI		S UNKNOWN			GILEAD	
Fatigue								
Nausea								
Vomiting								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10886829	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0140012		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Myocardial infarction		HARVONI		S UNKNOWN			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10886837	EXPEDITED (15-DAY)		HO,OT	DE- GILEAD-2015-0139463		Female	DEU
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Abdominal pain upper Aphagia Cholelithiasis Gamma-glutamyltransferase increased		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10886883	NON-EXPEDITED			US-PFIZER INC-2015070343		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Aspartate aminotransferase increased Alanine aminotransferase increased		Lipitor HARVONI		S S	UNK UNK		PFIZER	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10887139	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0139947	59 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Cardiac failure congestive		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10887140	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0139948	54 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Cardiac failure congestive		HARVONI		S UNKNOWN			GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10887471	EXPEDITED (15-DAY)			US- GILEAD-2015-0140540		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia Dizziness		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10887472	EXPEDITED (15-DAY)			US- GILEAD-2015-0140365	63 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Accidental overdose		HARVONI HARVONI		S ORAL S UNKNOWN	1 DF, BID UNK		GILEAD GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10887506	EXPEDITED (15-DAY)			US- GILEAD-2015-0140328		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash Headache		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10887508	EXPEDITED (15-DAY)			US- GILEAD-2015-0140511	61 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10887552	EXPEDITED (15-DAY)			US- GILEAD-2015-0140503	54 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10887670	EXPEDITED (15-DAY)			US- GILEAD-2015-0140296		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Allergic sinusitis		HARVONI LORATADINE		S UNKNOWN C	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10887677	EXPEDITED (15-DAY)			US- GILEAD-2015-0140292	64 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Confusional state Memory impairment Sleep disorder		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10887680	EXPEDITED (15-DAY)			US- GILEAD-2015-0140212	60 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10887732	EXPEDITED (15-DAY)			US- GILEAD-2015-0139353	65 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue Local swelling		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10903354	DIRECT				54 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Palpitations		HARVONI 90-400MG GILEAD SCIENCES		S ORAL			GILEAD	
Upper respiratory tract infection Bronchitis Influenza like illness		LYRICA		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10903779	DIRECT	Y	OT		52 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Breast pain		HARVONI 90/400MG GILEAD PRILOSEC CENTRUM SPIRIVA INHALER		S ORAL C C C	one tablet QD		GILEAD	
Breast swelling								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10904068	DIRECT				60 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Anxiety		HARVONI 90-400MG GILEAD SCIENCES		S ORAL			GILEAD	
Abnormal dreams								
Fatigue								
Mood altered								
Sleep disorder								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2015	10904586	DIRECT		OT		56 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea		HARVONI 90-400MG GILEAD SCIENCES		S ORAL			GILEAD	
Headache		STRIBILD		C				
Fatigue		LORAZEPAM		C				
Irritability		TEMAZEPAM		C				
		CIALIS		C				



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2015	10792590	EXPEDITED (15-DAY)		DE,OT	US- GILEAD-2015-0136997	67 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Death		HARVONI		S ORAL	1 DF, UNK		GILEAD	
Abdominal pain		ZIAGEN		C ORAL	300 mg, UNK			
Vomiting		NORVIR		C ORAL	100 mg, UNK			
Malaise		REYATAZ		C ORAL	300 mg, UNK			
Fatigue		LYRICA		C ORAL	100 mg, UNK			
		VITAMIN D3		C ORAL	1000 IU, UNK			
		NEUROTIN 01003001/	/	C ORAL	600 mg, UNK			
		TIVICAY		C ORAL	50 mg, UNK			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2015	10871423	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015067195	54 YR	Male	FRA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Epilepsy		Aldactone		S ORAL	75 mg, 1x/day		PFIZER	
Amnesia		HARVONI		S ORAL	82 mg, 1x/day			
Confusional state		XEROQUEL		S ORAL	500 mg, 1x/day			
Disorientation		ATARAX		S ORAL	25 mg, as needed			
Aphasia		ADCIRCA		S ORAL	40 mg, 1x/day			
Agitation		DEPAKINE		S ORAL	400 mg, 2x/day			
		DEPAKINE		S ORAL	500 mg, 2x/day			
		COVERSYL		S ORAL	2.5 mg, 1x/day			
		LASILIX SPECIAL /00032601/		S ORAL	125 mg, 1x/day			
		IMOVANE		S ORAL	7.5 mg, 1x/day			
		NICOBION		S ORAL	1 g, 1x/day			
		PANTOPRAZOLE		S ORAL				



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2015	10882269	EXPEDITED (15-DAY)			US- GILEAD-2015-0139974		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Confusional state Dizziness Gait disturbance Headache		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2015	10888407	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2015-0139999		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Renal failure Alanine aminotransferase decreased		HARVONI VIREAD		S UNKNOWN S UNKNOWN	UNK		GILEAD GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2015	10889094	EXPEDITED (15-DAY)			US- GILEAD-2015-0140023		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Agitation Lip swelling Blood pressure increased		HARVONI WELLBUTRIN		S UNKNOWN C	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2015	10889098	EXPEDITED (15-DAY)			US- GILEAD-2015-0139643	48 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Somnolence		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2015	10889414	EXPEDITED (15-DAY)			US-GILEAD-2015-0139622	65 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2015	10889415	EXPEDITED (15-DAY)			US-GILEAD-2015-0139591	73 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Depression Abdominal distension Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2015	10889434	EXPEDITED (15-DAY)			US-GILEAD-2015-0140202		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood pressure increased Fatigue Headache		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2015	10889435	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0140287	57 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Diabetes mellitus Hyperglycaemia		HARVONI AMLODIPINE OMEPRAZOLE		S ORAL S ORAL C	1 DF, UNK 2.5 mg, UNK		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2015	10889436	EXPEDITED (15-DAY)			US- GILEAD-2015-0140430	56 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2015	10889445	EXPEDITED (15-DAY)		HO	US- GILEAD-2015-0140530	65 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chest pain Pain		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2015	10889447	EXPEDITED (15-DAY)		HO	US- GILEAD-2015-0140531	50 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2015	10866173	EXPEDITED (15-DAY)	Y	OT	DE2015GSK004348	50 YR	Male	DEU
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood HIV RNA increased		TRIUMEQ		S				
Drug interaction		HARVONI		S				
Viraemia		RIBAVIRIN (RIBAVIRIN)		S				



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2015	10891241	EXPEDITED (15-DAY)		HO	GB-009507513-1503GB R002183	47 YR	Unknown	GBR
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nephrotic syndrome		RIBAVIRIN		S			MERCK	
		HARVONI		S				
		SOFOSBUVIR		S				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2015	10892340	EXPEDITED (15-DAY)			US- GILEAD-2015-0139756	72 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea		HARVONI		S ORAL	1 DF, UNK		GILEAD	
Headache								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2015	10892864	EXPEDITED (15-DAY)		OT	IE- GILEAD-2015-0139958	69 YR	Female	IRL
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Urinary tract infection		HARVONI		S ORAL	1 DF, QD		GILEAD	
		RIBAVIRIN		S ORAL	1000 mg, UNK			
		SALBUTAMOL		C				
		OMEPRAZOLE		C				
		FLUOXETINE		C				
		SERETIDE		C				
		IBANDRONIC ACID		C				
		CEFUROXIME		C				
		ALDACTONE 00006201/		/ C				
		TEMAZEPAM		C				
		FRUSEMIDE 00032601/		/ C				



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2015	10892869	EXPEDITED (15-DAY)			US- GILEAD-2015-0139635	52 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2015	10892872	EXPEDITED (15-DAY)			US- GILEAD-2015-0139797		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Inappropriate schedule of drug administration		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2015	10893487	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0140039	62 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Aggression Agitation		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2015	10893778	EXPEDITED (15-DAY)			US- GILEAD-2015-0139932		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Urticaria Hypersensitivity Periorbital oedema		HARVONI		S UNKNOWN	UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2015	10893783	EXPEDITED (15-DAY)			US- GILEAD-2015-0139867	55 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2015	10894973	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2015-0140462		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Toxicity to various agents Nausea Drug interaction Fatigue		HARVONI DIGOXIN		S UNKNOWN S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2015	10894983	EXPEDITED (15-DAY)		HO	US- GILEAD-2015-0140528	64 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood bilirubin increased Jaundice		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2015	10895717	EXPEDITED (15-DAY)			US- GILEAD-2015-0140038	58 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Depression		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10763137	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2015-0135073	53 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Encephalopathy Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10777845	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0136092	69 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Mental impairment Confusional state Disorientation Feeling jittery Nausea		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10883454	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0140268		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Neutrophil count decreased		HARVONI		S UNKNOWN			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10887414	EXPEDITED (15-DAY)		HO,OT	CA- GILEAD-2015-0140120	71 YR	Female	CAN
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Bradycardia		HARVONI		S UNKNOWN	UNK		GILEAD	
Atrioventricular block complete		AMIODARONE		S UNKNOWN	UNK			
Hypotension		BISOPROLOL		S UNKNOWN	UNK			
Syncope		FUROSEMIDE		C				
		LACTULOSE		C				
		ASPIRIN /		C				
		00002701/						
		SYMBICORT		C				
		L THYROXIN		C				
		TELMASURGE		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10896693	EXPEDITED (15-DAY)		HO	GB-ROCHE-1548658	47 YR	Unknown	GBR
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nephrotic syndrome		Ribavirin		S UNKNOWN				
		HARVONI		S UNKNOWN				
		SOFOSBUVIR		S UNKNOWN				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10898170	EXPEDITED (15-DAY)			US- GILEAD-2015-0140545		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash generalised		HARVONI		S UNKNOWN			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10898870	EXPEDITED (15-DAY)			US- GILEAD-2015-0140781		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Abdominal pain Headache Insomnia		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10898875	EXPEDITED (15-DAY)			US- GILEAD-2015-0140904	59 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10898879	EXPEDITED (15-DAY)			US- GILEAD-2015-0140797	54 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10898887	EXPEDITED (15-DAY)			US- GILEAD-2015-0141002		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Tinnitus		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899309	EXPEDITED (15-DAY)			US- GILEAD-2015-0139158	60 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899380	EXPEDITED (15-DAY)			US- GILEAD-2015-0140140		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Overdose		HARVONI		S UNKNOWN	2 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899381	EXPEDITED (15-DAY)			US- GILEAD-2015-0139595	34 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nasopharyngitis Oropharyngeal pain		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899384	EXPEDITED (15-DAY)			US- GILEAD-2015-0140162		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899395	EXPEDITED (15-DAY)			US- GILEAD-2015-0140127	59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Influenza like illness Pain		HARVONI		S UNKNOWN			GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899398	EXPEDITED (15-DAY)			US- GILEAD-2015-0140461	61 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Eye swelling		HARVONI		S UNKNOWN	UNK		GILEAD	
Rash generalised		KEPPRA		S UNKNOWN				
Drug interaction								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899401	EXPEDITED (15-DAY)			US- GILEAD-2015-0140416	65 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
Anxiety								
Fatigue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899402	EXPEDITED (15-DAY)			US- GILEAD-2015-0140247	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Flatulence		HARVONI		S ORAL	1 DF, QD		GILEAD	
Diarrhoea								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899403	EXPEDITED (15-DAY)			US- GILEAD-2015-0140388		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Myalgia		HARVONI		S UNKNOWN			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899404	EXPEDITED (15-DAY)			US-GILEAD-2015-0140477	57 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sleep disorder		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899405	EXPEDITED (15-DAY)			US-GILEAD-2015-0140446		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899406	EXPEDITED (15-DAY)			US-GILEAD-2015-0140401		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dyspepsia		HARVONI		S			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899409	EXPEDITED (15-DAY)			US-GILEAD-2015-0140488	52 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Middle insomnia Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899410	EXPEDITED (15-DAY)			US-GILEAD-2015-0140734		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S UNKNOWN	UNK		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899412	EXPEDITED (15-DAY)			US- GILEAD-2015-0140809		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Alopecia		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899414	EXPEDITED (15-DAY)			US- GILEAD-2015-0140493	62 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Fatigue		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899416	EXPEDITED (15-DAY)			US- GILEAD-2015-0140739		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899417	EXPEDITED (15-DAY)			US- GILEAD-2015-0140799	64 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899422	EXPEDITED (15-DAY)			US- GILEAD-2015-0141219	64 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Abdominal pain		HARVONI		S ORAL	1 DF, QD		GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899423	EXPEDITED (15-DAY)			US- GILEAD-2015-0141206	56 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pyrexia Constipation Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899424	EXPEDITED (15-DAY)			US- GILEAD-2015-0141224		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sinusitis		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899425	EXPEDITED (15-DAY)			US- GILEAD-2015-0141192		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Respiratory tract infection		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899426	EXPEDITED (15-DAY)			US- GILEAD-2015-0141213	46 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Gastrointestinal disorder Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899428	EXPEDITED (15-DAY)			US- GILEAD-2015-0140803		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash generalised		HARVONI		S ORAL	1 DF, UNK		GILEAD	
Pruritus		HCTZ		C				
		LEVOXYL		C				
		PROZAC		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899429	EXPEDITED (15-DAY)			US- GILEAD-2015-0141202		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood pressure increased		HARVONI		S UNKNOWN			GILEAD	
Blood pressure fluctuation								
Visual impairment								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899431	EXPEDITED (15-DAY)			US- GILEAD-2015-0141246	52 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
Fatigue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10899432	EXPEDITED (15-DAY)			US- GILEAD-2015-0141287		Unknown	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hepatitis C virus test positive		HARVONI		S UNKNOWN	UNK		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10905042	DIRECT		OT		60 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Muscle spasms			HARVONI	S ORAL				
Energy increased			VITAMIN D 1000 MG	C				
Indifference			POLICOSANOL	C				
			VICODIN	C				
			SCIALICA	C				
			ALPHA LIPOIC ACID	C				
Fatigue								
Muscle tightness								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10905188	DIRECT	Y			62 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia			HARVONI 90-400MG GILEAD SCIENCES	S ORAL			GILEAD	
			ALPRAZOLAM	C				
			ATENOLOL	C				
			METHADINE	C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10905258	DIRECT	Y	HO,LT		45 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Suicide attempt			HARVONI	S ORAL		1 MTH	GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10905631	DIRECT		DS,LT,OT,RI		57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Vomiting		HARVONI		S				
Nervous system disorder		LYICA		C				
Abasia		HYTROCLORITHY TRAMDOL		C				
Malaise		LEXPRO		C				
Muscular weakness		PROLOSEC		C				
Mental disorder		ZANAFLEX		C				
		XLEXDTIL		C				
		EQUATE		C				
Abnormal behaviour								
Diarrhoea								
Fall								
Impaired driving ability								
Pain								
Tremor								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10906907	DIRECT	Y			60 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Abdominal pain		HARVONI 90-400MG TAB GILEAD SCIENCES		S	ORAL			
Fatigue								
Flatulence								



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10906970	DIRECT	Y			51 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia Mood swings		HARVONI		S ORAL	1 tablet		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10907403	DIRECT	Y	HO		67 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Cerebrovascular accident Pulmonary thrombosis		HARVONI 90-400 MG		S ORAL			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2015	10911597	DIRECT	Y	HO		74 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Transfusion		HARVONI 90/400 MG GILEAD		S ORAL			GILEAD	



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2015	10711467	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0130084	61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Renal impairment	HARVONI	S	ORAL	1 DF, UNK		GILEAD		
	ASPIRIN (E.C.)	C	ORAL	325 mg, UNK				
	FLOMAX 01280302/	/	C	0.4 mg, UNK				
	ATARAX 00058402/	/	C	50 mg, UNK				
	LINZESS		C	145 µg, UNK				
	ATIVAN		C	1 mg, UNK				
	MEVACOR		C	40 mg, UNK				
	METHADONE HCL		C	5 mg/5 ml				
	MULTIPLE VITAMINS WITH MINERALS		C					
	METAMUCIL 00091301/	/	C	0.52 g, UNK				
	ZANTAC		C	150 mg, UNK				



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2015	10731168	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2015-0131733	55 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Cerebrovascular accident	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD		
Migraine	FUROSEMIDE	C		40 mg, BID				
Hypertension	LISINAPRIL	C		20 mg, BID				
Headache	METOPROLOL	C		12.5 mg, UNK				
	BABY ASPIRIN	C						
	CETIRIZINE	C						
	LORAZEPAM	C						
	ALBUTEROL / 00139501/	C						
	METOCARBAMOL	C						
	HYDROCODONE W/ PARACETAMOL	C						
	RANITIDINE	C						
	FORMOTEROL W/MOMETASONE	C						



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2015	10899972	EXPEDITED (15-DAY)		HO	IE-ROCHE-1549227	61 YR	Male	IRL
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Somnolence		Copegus		S	ORAL			
Asthenia		HARVONI		S	ORAL	400mg/90mg		
Encephalopathy		KIVEXA		S	UNKNOWN	600mg/300mg		
Lower respiratory tract infection		PREZISTA		S	ORAL			
Fluid retention		NORVIR		S	ORAL			
		SEPTRIN		S	UNKNOWN			
		METHADONE		C	UNKNOWN			
		LAXOSE		C	UNKNOWN			
		FUROSEMIDE		C	UNKNOWN			
		Diazepam		C	UNKNOWN	Nocte		
		CALCICHEW D3 FORTE		C	UNKNOWN	544mg/400 units		
		THIAMINE		C	UNKNOWN			
		GALFER		C	UNKNOWN			
		LANSOPRAZOLE		C	UNKNOWN			
		NeoRecormon		C	SUBCUTANEOUS			
		VERSATIS		C	UNKNOWN	1 patch applied daily for 12 hours		



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2015	10901586	EXPEDITED (15-DAY)		OT	IE- GILEAD-2015-0140052	49 YR	Female	IRL
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Encephalopathy		HARVONI		S ORAL	OD		GILEAD	
		RIBAVIRIN		S ORAL	600 mg, BID			
		CITALOPRAM 00582602/	/	C	20 mg, QD			
		CITALOPRAM 00582602/	/	C	40mg OD			
		THIAMINE 00056102/	/	C	UNK			
		OMEPRAZOLE		C	UNK			
		FRUSEMIDE		C	UNK			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2015	10901723	EXPEDITED (15-DAY)			US- GILEAD-2015-0140496	60 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Insomnia Fatigue Headache		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2015	10901728	EXPEDITED (15-DAY)			US- GILEAD-2015-0140999		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Tinnitus		HARVONI		S UNKNOWN			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2015	10901816	EXPEDITED (15-DAY)			US- GILEAD-2015-0141000	50 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Tinnitus		HARVONI GABAPENTIN		S UNKNOWN C			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2015	10902176	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2015-0140786		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hepatic failure Blood bilirubin increased		HARVONI RIBAVIRIN		S UNKNOWN S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2015	10902872	EXPEDITED (15-DAY)			US- GILEAD-2015-0140455		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hepatitis C RNA positive		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2015	10902927	EXPEDITED (15-DAY)		OT	CA- GILEAD-2015-0140763	49 YR	Male	CAN
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dermatitis bullous Rash pruritic		HARVONI		S UNKNOWN			GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2015	10912771	DIRECT	Y			33 YR	Male	
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Hot flush Body temperature increased Hyperhidrosis		HARVONI		S	ORAL	one tablet		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2015	10912916	DIRECT	Y			62 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Headache Headache Pruritus		HARVONI 90-400 MG		S	ORAL	1 pill	8 WEEK	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2015	10905782	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0141103		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Hepatitis C Drug ineffective		HARVONI		S	UNKNOWN	UNK		GILEAD
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2015	10905834	EXPEDITED (15-DAY)		HO	US- GILEAD-2015-0140893	54 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
White blood cell count increased Blood alkaline phosphatase increased Blood bilirubin increased		HARVONI		S	UNKNOWN	UNK		GILEAD



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2015	10905845	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0140892		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood alkaline phosphatase increased Hepatic enzyme increased		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2015	10906027	EXPEDITED (15-DAY)		OT	DE- GILEAD-2015-0141449		Male	DEU
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Liver transplant		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2015	10906395	EXPEDITED (15-DAY)			US- GILEAD-2015-0137572	49 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Vision blurred		HARVONI		S ORAL	1 UNK, UNK		GILEAD	
Hyperkalaemia		ALBUTEROL 00139501/		/ C				
Sinusitis		ATIVAN		C				
		PAROXETINE		C				
		ALLOPURINOL		C				
		ROPINIROLE		C				
		IRON		C				
		LASIX		/00032601/ C				
		RANITIDINE		C				
		LACTULOSE		C				
		BIAXIN		C				



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2015	10908819	EXPEDITED (15-DAY)		DE,OT	AT- GILEAD-2015-0141490		Male	AUT
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sepsis Multi-organ failure Nephropathy		HARVONI		S UNKNOWN			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2015	10911211	EXPEDITED (15-DAY)		HO,OT	GB- GILEAD-2015-0140638	47 YR	Unknown	GBR
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nephrotic syndrome		HARVONI RIBAVIRIN		S UNKNOWN S UNKNOWN	UNK UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2015	10763783	EXPEDITED (15-DAY)			US- GILEAD-2015-0134909		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Erectile dysfunction Diarrhoea Headache		HARVONI		S UNKNOWN	UNK DF, UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2015	10914621	EXPEDITED (15-DAY)			US- GILEAD-2015-0140908	57 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache Insomnia		HARVONI		S ORAL	1 DF, QD		GILEAD	



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2015	10914625	EXPEDITED (15-DAY)		HO,OT	IE-GLAXOSMITHKLINE-IE2015030209	61 YR	Male	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Somnolence	Kivexa	S		600mg/300mg		VIIV
Asthenia	Septrin	S				GLAXOSMITHKLINE
Encephalopathy	HARVONI	S	ORAL	400mg/90mg		
Asterixis	COPEGUS	S				
Lower respiratory tract infection	PREZISTA	S				
Fluid retention	NORVIR	S				
	METHADONE	C				
	LAXOSE	C				
	FUROSEMIDE	C				
	DIAZEPAM	C		Nocte		
	CENTRUM	C				
	CALCICHEW-D3 FORTE	C		544mg/400 units		
	THIAMINE	C				
	GALFER	C				
	LANSOPRAZOLE	C				
	NEORECORMON	C	SUBCUTANEOUS			
	VERSATIS	C		1 patch applied daily for 12 hours		
	MOVICOL	C				
	LACRI-LUBE EYE OINTMENT	C				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2015	10914660	EXPEDITED (15-DAY)			US-GILEAD-2015-0140995		Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Dysphagia	HARVONI	S	ORAL			GILEAD
Product size issue						



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2015	10914663	EXPEDITED (15-DAY)			US- GILEAD-2015-0140787	63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2015	10914783	EXPEDITED (15-DAY)		HO,LT,OT	IE- GILEAD-2015-0141025	51 YR	Male	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Meningitis tuberculous	HARVONI	S	ORAL	1 DF, QD		GILEAD
Meningitis cryptococcal	RIBAVIRIN	S	ORAL	1 DF, UNK		
	ALDACTONE 00006201/	/	C			
	FRUSEMIDE 00032601/	/	C			
	THIAMINE		C			
	PARACETAMOL		C			
	RIFAXIMIN		C			
	PROPANOLOL 00030001/	/	C			
	OMEPRAZOLE		C			
	LACTULOSE		C			
	MOVICOL 01749801/	/	C			
	CIPROFLOXACIN		C			



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2015	10907893	EXPEDITED (15-DAY)		HO	IE- ABBVIE-15P-229-135795 5-00	61 YR	Male	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Encephalopathy	NORVIR	S	UNKNOWN			
Lower respiratory tract infection	HARVONI	S	ORAL	400mg/90mg		
Asterixis	COPEGUS	S	UNKNOWN			
Somnolence	KIVEXA	S	UNKNOWN	600mg/300mg		
Fluid retention	PREZISTA	S	UNKNOWN			
Asthenia	SEPTRIN	S	UNKNOWN			
	METHADONE	C				
	LAXOSE	C				
	FUROSEMIDE	C				
	DIAZEPAM	C		Nocte		
	CENTRUM	C		1 dosage forms		
	CALCICHEW-D3 FORTE	C		544mg/400units		
	THIAMINE	C				
	GALFER	C				
	LANSOPRAZOLE	C				
	NEORECORMON	C	SUBCUTANEOUS			
	VERSATIS	C		1 patch applied daily for 12 hours		
	MOVICOL	C		2 dosage forms		
	LACRI-LUBE	C	OPHTHALMIC			



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2015	10789736	EXPEDITED (15-DAY)		HO	IE- GILEAD-2015-0136307	60 YR	Male	IRL
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Confusional state		HARVONI		S ORAL	1 DF, QD		GILEAD	
Asterixis		COPEGUS		C	UNK			
		TARGAXAN		C	UNK			
		LAXOSE		C	UNK			
		PINADONE		C	UNK			
		DIAZEPAM		C				
		DALMANE		C	UNK			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2015	10790970	EXPEDITED (15-DAY)		HO,OT	IE- GILEAD-2015-0136292	55 YR	Male	IRL
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hepatic encephalopathy		HARVONI		S ORAL	1 DF, QD		GILEAD	
Coma scale abnormal		COPEGUS		C	400 mg, QD			
		COPEGUS		C	600 mg, QD			
		TARGAXAN		C	550 mg, BID			
		LAXOSE		C	30 ml, TID			
		BENERVA		C	100 mg, TID			
		LANSOPRAZOLE		C	15 mg, QD			
		PINADONE		C	25 mg, UNK			
		HEPA MERZ		C				



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2015	10844763	EXPEDITED (15-DAY)		DE,OT	US- GILEAD-2015-0138415	65 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Ischaemic enteritis		HARVONI		S	UNKNOWN	1 DF, QD		GILEAD
Mesenteric artery thrombosis		COCAINE		S	UNKNOWN			
Hepatic infarction								
Pneumonia aspiration								
Renal failure acute								
Splenic infarction								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2015	10856402	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2015-0137910	46 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Transient ischaemic attack		HARVONI		S	ORAL	400 mg, QD		GILEAD
Contusion								
Convulsion								
Dizziness								
Fall								
Memory impairment								
Syncope								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)**

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2015	10872265	EXPEDITED (15-DAY)		HO,OT	DE- GILEAD-2015-0138879	59 YR	Female	DEU
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Upper gastrointestinal haemorrhage		HARVONI		S ORAL	1 DF, QD		GILEAD	
Haemorrhagic anaemia		TOREM / 01036501/		C ORAL	200 mg, UNK			
Anaemia		SPIRONOLACTONE		C ORAL	25 mg, UNK			
Varices oesophageal		PANTOZOL / 01263204/		C ORAL	40 mg, UNK			
Oesophageal ulcer								
Pneumonia								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2015	10911199	EXPEDITED (15-DAY)		OT	DE- GILEAD-2015-0140932	39 YR	Male	DEU
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Aspartate aminotransferase increased		HARVONI		S ORAL	1 DF, QD		GILEAD	
Gamma-glutamyltransferase increased		TRUVADA		S ORAL	1 DF, QD		GILEAD	
		TRUVADA		S			GILEAD	
		PREZISTA		C ORAL	800 mg, QD			
		NORVIR		C ORAL	100 mg, QD			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2015	10781563	EXPEDITED (15-DAY)			US- GILEAD-2015-0136015	60 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Flatulence		HARVONI		S ORAL	1 DF, QD		GILEAD	
Abdominal pain								
Asthenia								
Diarrhoea								
Fatigue								



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Mar-2015	10836030	EXPEDITED (15-DAY)			US- GILEAD-2015-0137117	43 YR	Female	USA	
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>		<u>Dosage Text</u>		<u>Duration</u>	<u>Manufacturer</u>
Alopecia		HARVONI		S ORAL		1 DF, QD			GILEAD
Abdominal pain upper									
Diarrhoea									
Dyspepsia									
Fatigue									
Headache									
Nausea									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Mar-2015	10911202	EXPEDITED (15-DAY)		HO	FR- GILEAD-2015-0135832	75 YR	Female	FRA	
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>		<u>Dosage Text</u>		<u>Duration</u>	<u>Manufacturer</u>
Neutropenia		HARVONI		S UNKNOWN		UNK			GILEAD
		COAPROVEL		C ORAL		300 mg, UNK			
		EZETROL		C ORAL		10 mg, UNK			
		INEXIUM 01479302/		C ORAL		20 mg, UNK			
		LEVOTHYROX		C ORAL		100 µg, UNK			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
19-Mar-2015	10746501	EXPEDITED (15-DAY)			US- GILEAD-2015-0134076	64 YR	Female	USA	
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>		<u>Dosage Text</u>		<u>Duration</u>	<u>Manufacturer</u>
Tinnitus		HARVONI		S UNKNOWN		UNK			GILEAD



**FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report**

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2015	10865932	EXPEDITED (15-DAY)			US- GILEAD-2015-0138668		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dyspnoea		HARVONI		S ORAL	1 DF, QD		GILEAD	
Feeling abnormal		PANTOPRAZOLE		C				
Oedema peripheral		FUROSEMIDE		C				
Speech disorder		TAMSULOSIN		C				
Dysphonia		VALSARTAN		C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2015	10911198	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0141197		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Seizure like phenomena		HARVONI		S UNKNOWN	UNK, QD		GILEAD	
Headache								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2015	10902612	EXPEDITED (15-DAY)		HO,OT	US- GILEAD-2015-0140712	67 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Syncope		HARVONI		S ORAL	1 DF, QD		GILEAD	
Sinus bradycardia		PROPAFENONE		S ORAL	425 mg, UNK			
Trifascicular block		METOPROLOL SUCCINATE		S ORAL	50 mg, QD			
		VERAPAMIL		S ORAL	200 mg, QD			
		ASPIRIN 81		C ORAL	81 mg, QD			



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2015	10717623	EXPEDITED (15-DAY)			US- GILEAD-2015-0130998	59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Diarrhoea Anxiety		HARVONI		S ORAL	1 DF, QD		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2015	10759652	EXPEDITED (15-DAY)			US- GILEAD-2015-0134395	53 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dysphagia Oropharyngeal pain Wrong technique in drug usage process		HARVONI		S UNKNOWN	UNK		GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2015	10836048	EXPEDITED (15-DAY)			US- GILEAD-2015-0137151	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chromaturia Dysuria		HARVONI CURAMIN		S UNKNOWN C			GILEAD	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2015	10856494	EXPEDITED (15-DAY)		OT	US- GILEAD-2015-0137532		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Aspartate aminotransferase increased Alanine aminotransferase increased		HARVONI		S ORAL	1 DF, QD		GILEAD	