

HARVONI® Tablets

Ledipasvir/sofosbuvir
90 mg/400 mg tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

Read all of this leaflet carefully before you start taking this medicine.

This leaflet answers some of the common questions about HARVONI tablets. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist about your medical condition or treatment. If you have further questions, please ask your doctor or your pharmacist.

Keep this leaflet with your HARVONI medicine. You may need to read it again.

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

WHAT IS HARVONI

HARVONI is one tablet that contains two active substances, ledipasvir and sofosbuvir, which are given to treat hepatitis C virus infection in adults of 18 years and older.

Hepatitis C is a virus that infects the liver. This medicine works by lowering the amount of hepatitis C virus in your body and may lead to a cure of your HCV infection over a number of weeks.

Cure means the HCV virus is cleared from your blood (remains at an undetectable level) when measured 3 months after finishing all treatment.

HARVONI is for adults. HARVONI has not been studied in children under the age of 18.

BEFORE YOU TAKE HARVONI

Who should not take HARVONI

Together with your doctor, you need to decide whether HARVONI is right for you.

Do not take HARVONI if you are allergic to ledipasvir, sofosbuvir or any of the other ingredients of HARVONI. The ingredients of HARVONI are listed in the product description section of this leaflet.

Do not take HARVONI if you are taking any medicine other than HARVONI that contains sofosbuvir.

If you are pregnant think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not breastfeed during treatment with HARVONI.

What should I tell my doctor before taking HARVONI

Tell your doctor if you:

Take any of the following medicines:

- amiodarone used to treat heart conditions

- digoxin used to treat heart conditions
- rosuvastatin used to treat high cholesterol
- tipranavir used to treat HIV infection
- tenofovir disoproxil fumarate used to treat HIV infection

HARVONI may interact with these medicines. As a result, the amounts of HARVONI or other medicines in your blood may be affected. This may stop your medicines from working properly, or make any side effects worse. In some cases your doctor may need to give you a different medicine or adjust the dose of medicine you are taking.

Take any of the following medicines:

- rifampicin, rifapentine, rifabutin (antibiotics used to treat infections, including tuberculosis);
- St. John's Wort (*Hypericum perforatum* - herbal medicine used to treat depression);
- carbamazepine, phenytoin (medicines used to treat epilepsy and prevent seizures).

This is because they may make HARVONI work less well.

Take any medicines used to treat stomach ulcers, heartburn or acid reflux, such as:

- antacids (e.g. aluminium hydroxide or magnesium hydroxide)
- proton pump inhibitors (e.g. omeprazole)

- H2-antagonists (e.g. famotidine). These medicines can decrease the amount of ledipasvir in your blood. If you are taking one of these medicines your doctor will either give you a different medicine for stomach ulcers, heartburn or acid reflux, or recommend how and when you take that medicine.

If you are taking an antacid, take it at least 4 hours before or at least 4 hours after HARVONI.

If you are taking a proton pump inhibitor, take it at the same time as HARVONI or up to 2 hours after taking HARVONI. Do not take before HARVONI.

If you are taking an H2-antagonist, your doctor may give you a different medicine or adjust the dose of the medicine you are taking.

- Are allergic to foods, dyes, preservatives or any other medicines
- Are breastfeeding or plan to breastfeed. It is not known whether ledipasvir or sofosbuvir, the two active substances of TRADENAME, pass into human breast milk
- Have liver problems, other than hepatitis C
- Have hepatitis B
- Have any other medical condition
- Have severe kidney problems or if you are on haemodialysis as the effects of HARVONI on patients with severe kidney problems have not been fully tested.

WHAT IMPORTANT INFORMATION SHOULD I KNOW ABOUT TAKING OTHER MEDICINES WITH HARVONI

It is very important to let your doctor or pharmacist know what medications, herbal supplements, or vitamins you are taking.

Know the medicines you take. Keep a list of medicines and show it to your doctor and pharmacist when you get a new medicine. Your doctor and your pharmacist can tell you if you can take these medicines with HARVONI. Do not start any new medicines while you are taking HARVONI without first talking with your doctor or pharmacist.

HOW TO TAKE HARVONI

The usual dose is one HARVONI tablet orally, once daily. Never change the dose on your own. Do not stop this medicine unless your doctor tells you to stop.

If you forget to take HARVONI

Do not miss a dose of HARVONI. If you forget to take HARVONI, take your missed dose right away unless it is almost time for your next dose.

Do not take a double dose to make up for a forgotten dose. Continue with your regular dosing schedule.

Do not stop taking HARVONI unless your doctor tells you to. It is very important that you complete the full course of treatment to give the medicines the best chance to cure your hepatitis C virus infection.

Do not change your dose or stop taking HARVONI without first talking to your doctor.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre: 13 11 26 (Australia) and 0800 764 766 (New Zealand) or go to the Accident and Emergency department at your nearest hospital if you think you or anyone else may have taken too many HARVONI tablets. Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.

Things you must not do

- Do not breastfeed. See "What should I tell my doctor before taking HARVONI".
- Do not take HARVONI after the expiry or "use by" date (EXP) printed on the bottle. If you take it after the expiry date has passed, it may not work as well.
- Do not take HARVONI if the packaging is torn or shows signs of tampering.

Things to be careful of

Be careful driving or operating machinery until you know how HARVONI affects you.

POSSIBLE SIDE EFFECTS

Like all medicines, HARVONI can have side effects, although not everybody gets them.

If you take HARVONI you may get one or more of the side effects below:

- tiredness
- headache
- nausea

Check with your doctor as soon as possible if you have any problems while taking HARVONI, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

SPONSOR

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Allergy

Some people are allergic to medicines. If you have any of the following symptoms soon after taking your medicine, **DO NOT TAKE ANY MORE HARVONI** and tell your doctor **IMMEDIATELY** or go to the accident and emergency department at your nearest hospital:

- Skin troubles such as lumpy skin rash or "hives"
- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- Wheezing, chest pain or tightness
- Fainting

These are very serious effects. If you have them, you may have a serious allergic reaction. You may need urgent medical attention or hospitalisation. Hypersensitivity reactions are very rare.

Ask your doctor or pharmacist if you don't understand anything in this list.

HOW DO I STORE HARVONI

Keep HARVONI tablets where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store them.

Keep HARVONI tablets in a cool, dry place where it stays below 30°C.

Do not store HARVONI or any other medicine in a bathroom or near a sink.

Do not leave HARVONI in the car or on a window sill - heat and dampness can destroy some medicines.

Keep your HARVONI tablets in the bottle with the cap tightly closed until you take them. If you take HARVONI tablets out of their pack they may not keep well.

GENERAL ADVICE ABOUT PRESCRIPTION MEDICINES

Talk to your doctor or pharmacist if you have any questions about this medicine or your condition.

Medicines are sometimes prescribed for conditions that are not mentioned in this leaflet. Do not use HARVONI for a condition for which it was not prescribed. Do not give HARVONI to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarises the most important information about HARVONI. If you would like more information, ask your doctor or pharmacist. Your doctor or pharmacist can give you information about this medicine that was written for doctors or pharmacists (Product Information/Datasheet).

PRODUCT DESCRIPTION

What HARVONI tablets look like

HARVONI tablets are diamond-shaped and orange in colour. Each tablet has "GSI" on one side and "7985" on the other side of the tablet.

HARVONI tablets are supplied in bottles containing 28 tablets.

HARVONI tablet ingredients

Active Ingredients: ledipasvir and sofosbuvir.

Inactive Ingredients: silicon dioxide, copovidone, croscarmellose sodium, lactose, magnesium stearate and microcrystalline cellulose.

Film-coating: polyvinyl alcohol, polyethylene glycol, titanium dioxide, talc purified, and sunset yellow FCF.