

REBETOL® CAPSULES

Ribavirin

Consumer Medicine Information

What is in this leaflet?

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

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using REBETOL Capsules against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may want to read it again.

What REBETOL is used for?

REBETOL Capsules contain an antiviral agent called ribavirin.

REBETOL Capsules are not effective when used alone and must only be used in combination with PEG-Intron® injections. The active ingredient in the PEG-Intron injections is peginterferon alfa-2b. Peginterferon alfa-2b belongs to a group of medicines called interferons.

Combination therapy with REBETOL Capsules is used for the treatment of chronic hepatitis C (a viral infection of the liver) in patients (18 years or older) who have compensated liver disease and have not previously received interferon alfa treatment, including patients who are co-infected with stable Human Immunodeficiency Virus (HIV).

Combination therapy with REBETOL Capsules makes the treatment of hepatitis C more effective than using PEG-Intron injections alone.

Before you use REBETOL Capsules

When you must not use it:

Do not use REBETOL Capsules if you are allergic to ribavirin or any of the ingredients listed at the end of this leaflet.

REBETOL Capsules are not suitable for patients with certain other past or present serious illness.

You must mention any past or present serious illness to your doctor.

Do not use REBETOL Capsules if you are or your partner is pregnant or planning to become pregnant - this applies to both female patients and to partners of male patients using REBETOL Capsules.

It is very important that you or your partner avoid becoming pregnant during treatment and for 6 months after treatment. This is because REBETOL Capsules can affect the sperm as well as the unborn child.

Do not use REBETOL Capsules if you are breastfeeding.

Do not use REBETOL Capsules if you have any of these medical conditions:

- serious heart problems during the last six months or any previous serious heart condition
- blood disorders including anaemia (low number of red blood cells), thalassaemia (Mediterranean anaemia), sickle-cell anaemia
- serious kidney problems
- serious liver problems other than chronic hepatitis C
- serious nervous or mental problems, such as severe depression or thoughts of suicide
- autoimmune hepatitis or any other problem with your immune system
- thyroid disease that is not well controlled with medicines.

Do not use REBETOL Capsules if you are presently taking or have been treated recently with medications that suppress the immune system.

This includes body organ transplant recipients.

Do not use REBETOL Capsules if you have any of the following hereditary disorders:

- Galactose intolerance (the body is unable to absorb galactose)
- Lapp lactase deficiency (the body is unable to digest milk and milk products)
- Glucose-galactose malabsorption (the small intestine is unable to transport and absorb glucose and galactose).

If you are unable to use REBETOL Capsules, your hepatitis C may still be treated with PEG-Intron injections alone.

Do not use REBETOL Capsules:

- **if the packaging is torn or shows signs of tampering.**
- **after the expiry date (EXP) printed on the packs has passed. If you use it after the expiry date it may not work as well.**

If you are not sure whether you should start using REBETOL Capsules, talk to your doctor.

Before you start to use it

If you are or your partner is a woman of childbearing age, you or your partner must have a negative pregnancy test before treatment with REBETOL Capsules starts.

You or your partner must also have a negative pregnancy test each month during treatment and for the 6 months after treatment is stopped.

Two effective forms of contraception must be used, one by each partner, male and female, during treatment with REBETOL Capsules and for the 6 months after treatment is completed. REBETOL Capsules can cause harm to the unborn child if a pregnant woman takes REBETOL Capsules herself during pregnancy or has unprotected sex (sex without using a condom) with a man who is taking REBETOL Capsules. REBETOL Capsules can damage the sperm and the embryo (unborn child).

Do not use REBETOL Capsules if you are breastfeeding.

Your doctor may request liver and kidney function tests before starting your treatment, especially if you are older than 65 years or if you have problems with your liver and/or kidneys.

Your doctor may also request tests of your heart function before starting treatment, especially if you have problems with your heart.

Your doctor may ask you to have an eye examination before starting treatment.

You must tell your doctor:

1. **if you are allergic to any other medicines or any food, dyes or preservatives.**
2. **if you have any of these medical conditions:**
 - congestive heart failure, irregular or very fast heartbeat, heart disease, or you have ever had a heart attack or other heart problems
 - hypertriglyceridaemia (or high triglycerides levels in the blood)
 - a history of diabetes or lung disease
 - blood clotting disorder
 - psoriasis
 - sarcoidosis
 - kidney problems
 - liver problems (besides hepatitis C)
 - thyroid disease
 - eye problems
 - gout
 - organ transplant
 - HIV positive
 - depression or any other mental disorders
 - substance use disorder.
3. **if you have or have had serious nervous or mental problems, such as severe depression, thoughts of suicide or any other psychiatric disorder**

4. **if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.**

5. **Tell your doctor if you are taking antiviral medications for HIV infection (e.g. didanosine, abacavir) as co administration with REBETOL Capsules is not recommended and will need to be monitored.**

6. **Tell your doctor if you are taking theophylline for asthma, as you may need to take different amounts of your medicine.**

7. **Tell your doctor if you are taking shosaikoto, a Chinese herbal medicine. Lung problems such as shortness of breath and pneumonia have been reported more frequently if shosaikoto is taken with a form of interferon.**

Please read the Consumer Medicine Information for PEGATRON Combination Therapy for other things to be careful of when REBETOL Capsules are used in combination with PEG-Intron Injections.

Use in Children

REBETOL Capsules are not recommended for use in patients under 18 years of age.

How to use REBETOL Capsules

Use REBETOL Capsules exactly as your doctor has directed.

Routine blood tests will help your doctor to monitor your response to treatment.

Do not exceed the recommended dosage.

How many REBETOL Capsules to take

Your doctor has determined the dose of REBETOL Capsules based on your weight. For patients weighing:

- less than 65 kg, the usual dose is 2 capsules in the morning and 2 capsules in the evening.
- 65 kg to 85 kg, the usual dose is 2 capsules in the morning and 3 capsules in the evening.
- over 85 kg to 105 kg, the usual dose is 3 capsules in the morning and 3 capsules in the evening.
- Over 105 kg, the usual dose is 3 capsules in the morning and 4 capsules in the evening.

Your doctor may adjust your dose during therapy according to your response.

In some cases, your doctor may reduce the dosage to one capsule in the morning and 2 capsules in the evening.

How to take the capsules

REBETOL Capsules should be taken with food.

Swallow the capsules whole with water.

How long to use REBETOL Capsules

Treatment should be for at least 12 weeks and for up to 1 year depending on your response.

For HCV/HIV co-infected patients, the recommended duration of treatment is 48 weeks.

Do not stop using this medicine without first checking with your doctor.

Your doctor will determine when your treatment should be stopped.

If you become pregnant while using REBETOL Capsules, you should immediately stop the treatment and tell your doctor. If your partner becomes pregnant while you are using REBETOL Capsules, ask your partner to tell her doctor immediately.

If you forget to use REBETOL Capsules

If you miss a dose of REBETOL Capsules,

- take the missed dose as soon as possible during the same day.
- If an entire day has gone by, check with your doctor.

Do not double the next dose to make up for the dose that you missed.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone number for Australia: 13 11 26, or New Zealand: 0800 764 766) for advice, or go to casualty at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

While you are using REBETOL Capsules

Things you must do

Use REBETOL Capsules exactly as your doctor has prescribed.

Tell your doctor immediately if you have an allergic reaction.

Symptoms of an allergic reaction may include:

- hives, itching or skin rash

- swelling of the face, lips or tongue. This may lead to difficulty in swallowing.
- shortness of breath, wheezing, difficulty in breathing or a tight feeling in your chest.

Tell all doctors, dentists and pharmacists who are treating you that you are using REBETOL Capsules.

Stop using REBETOL Capsules if you become pregnant and immediately tell your doctor. If your partner becomes pregnant while you are using REBETOL Capsules, ask your partner to tell her doctor immediately.

Keep all your doctor's appointments so that your progress can be checked. Your doctor will carry out blood tests to monitor your response to treatment.

Your doctor may ask you to have regular eye checks during treatment, especially if you are diabetic or have high blood pressure.

Make sure you brush your teeth twice daily and have regular dental checks while you are using REBETOL Capsules. If you experience vomiting, rinse your mouth thoroughly afterwards.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking REBETOL Capsules.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are using this medicine .

Things you must not do

REBETOL Capsules do not affect your ability to drive or use machines. However, PEG-Intron injections may cause dizziness and drowsiness in some people. If you become drowsy from the combination therapy, do not drive or use machinery.

Do not use it to treat any other complaints.

Do not give this therapy to anyone else, even if their symptoms seem similar to yours.

Do not let yourself run out of medicine over weekends or holiday periods.

Check with your doctor immediately:

- if you notice any signs of anaemia, such as tiredness, being short of breath, and looking pale.
- you think you are getting a cold or chest infection. While using REBETOL in combination therapy, you may temporarily have a greater risk of getting an infection.
- if you notice unusual bleeding or bruising.
Your blood may temporarily take a longer time to clot.

Tell your doctor if you notice:

- any changes in your eyes or eyesight even if there is no pain or discomfort
- signs of psoriasis for the first time or worsening of the disease

Your doctor may want you to drink extra fluids.

This will help prevent low blood pressure while you are on REBETOL Capsules in combination therapy.

If you are also taking antiviral medications for HIV infection, and suddenly develop unexplained/ abnormal sensation of shortness of breath, consult your doctor immediately. Stop using medications until you have checked with your doctor.

The shortness of breath sensation may be due to a condition known as "lactic acidosis" (high acid levels in the blood). This condition has been reported with some HIV (antiviral) medications.

Side effects

The side effects listed below are possible side effects to the combination of REBETOL Capsules and PEG-Intron injections. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using the combination therapy.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist any questions you may have.

Stop taking the combination therapy and tell your doctor immediately if you suddenly get an itchy rash, swelling of the face, lips or tongue, wheezing or troubled breathing or faintness.

These could be signs of a serious allergic reaction.

Check with your doctor immediately if any of the following side effects occurs:

- signs of anaemia such as tiredness, being short of breath and looking pale
- signs of liver decompensation such as a swollen abdomen, swelling of the legs, bruising, vomiting blood and difficulty is staying awake or alert
- lower back or side pain, painful difficult or frequent urination
- severe stomach pain
- severe nosebleed
- unusual bruising or bleeding (signs of bleeding include blood in stool or urine, or black or tar-like stools)
- fever or chills beginning after a few weeks of treatment
- persistent cough or shortness of breath
- problems with eyesight or hearing
- seizures
- depression, aggressive behaviour or suicidal feelings

- confusion, trouble sleeping, thinking or concentrating
- chest pain, or fast or irregular heartbeat
- numbness or tingling sensation.

You may need urgent medical attention.

Tell your doctor if you notice any of the following and they worry you:

- irritation, inflammation or pain at the site of the PEG-Intron injection
- flu-like symptoms such as headache, fatigue, fever and chills
- weakness, sleepiness
- flushing, increased sweating feeling faint or dizziness
- shaky hands
- increased or decreased sensitivity to touch
- dry or teary eyes
- sore mouth or tongue, dry mouth or taste change
- bleeding gums
- thirst
- weight loss, loss of appetite
- stomach pain, indigestion or constipation
- nausea (feeling sick), vomiting or diarrhoea/intestinal gas
- muscular ache and pain or joint pain
- pain on right side around your ribs
- gout
- tense muscles
- migraine
- nervousness, mood swings, anxiety, agitation irritability
- hair loss/change in hair texture, itching, rash or dry or redness of the skin
- skin sensitive to sunlight
- jaundice (yellow skin)
- problems with your thyroid function which may appear as facial puffiness, swelling around the eyes, intolerance to cold or weight loss, increased appetite and difficulty sleeping
- eye or ear pain/infection

- lack of interest in sex/inability to perform
- sore throat, cough, runny or stuffy nose
- viral or fungal infection
- menstrual problems or period pain
- mouth thrush
- back pain, limb pain.

These side effects may go away as your body adjusts to the medication. If they continue or are severe, tell your doctor.

Other side effects not listed above may also occur in some patients. If you notice any other side effects, check with your doctor.

Check with your doctor as soon as possible if you have any problems while using the combination therapy, even if you do not think the problems are connected with the medicines.

Do not be alarmed by the list of possible side effects. You may not experience any of them.

After using REBETOL Capsules

Storage

Keep REBETOL Capsules where children cannot reach.

Store REBETOL Capsules at room temperature (below 25°C).

Do not store the capsules in the bathroom or near a sink. Heat and dampness can destroy some medicines.

A locked cupboard at least 1.5 metres above the ground is a good place to store medicines.

Disposal

Return any unused medicine to your pharmacist.

Product description

What it looks like

REBETOL Capsules are white, opaque capsules with blue markings of "200 mg" and a stripe on one half of the capsule, and a "S-P" logo and a stripe on the other half. The capsules are packaged in blister packs of 84, 112, 140, 168 and 196 capsules.

Ingredients

Each REBETOL Capsule contains:

- ribavirin 200 mg
- microcrystalline cellulose
- lactose
- croscarmellose sodium
- magnesium stearate

The REBETOL capsule shell contains:

- gelatin
- titanium dioxide
- sodium lauryl sulfate
- silicon dioxide

Supplier

In Australia:

Merck Sharp & Dohme (Australia) Pty Limited
54-68 Ferndell Street
South Granville NSW 2142
AUSTRALIA

In New Zealand:

Merck Sharp & Dohme (New Zealand) Limited
PO Box 99851
Newmarket
Auckland 1149
New Zealand

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