

REBETOL[®] 200mg Capsules

REBETOL[®] (Ribavirin)

Consumer Medicine Information

May 2007

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 against the benefits they expect it will have for you.

Rebetol Capsules must always be taken in combination with Intron A. They must never be taken on their own.

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 (ribavirin) capsules are not effective when used alone and must only be used in combination with Intron A injections.

The combination of Rebetol capsules and Intron A Injection makes the treatment of hepatitis C (a viral infection of the liver) more effective.

Before you use Rebetol

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. (You may get hives or an itchy skin rash, swelling of the face, lips or tongue, wheezing or troubled breathing, faintness or other symptoms if you have it.)

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

You must tell your doctor:

1. if you have or have had any serious illness. Perhaps Rebetol treatment will not be suitable for you.
2. if you ever had a heart attack or a heart problem, severe liver diseases excluding chronic hepatitis C, thyroid problems; if you have ever been treated for depression or any other psychiatric disorder, confusion, unconsciousness, or have had thoughts of suicide or
3. if you have attempted suicide.
4. if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Use in Children

There is limited experience with the use of Rebetol capsules in children. Rebetol Capsules is not recommended for use in patients under 18 years old.

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

The usual dose for patients weighing 75 kg or less is 2 capsules in the morning and 3 capsules in the evening.

Patients weighing more than 75 kg would usually take 3 capsules in the morning and 3 capsules in the evening.

In some cases, the Rebetol dosage may have to be reduced. In that case, your doctor will tell you to take one capsule in the morning and 2 capsules in the evening.

How to take the capsules

Rebetol Capsules may be taken without regard to food, but should be taken in a consistent manner.

Swallow the capsules whole with water.

If you forget to take Rebetol

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 take a double dose to make up for a forgotten dose.

If you use too much (overdose)

If you think you or anyone else may have used too much Rebetol, 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. Rebetol Capsules must be taken in combination with Intron A . When the two medications are taken together the combination is called Rebetron Combination Therapy

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 Rebetron Combination Therapy.

Stop using Rebetol in combination with Intron A if you become pregnant and immediately tell your doctor. If your partner becomes pregnant while you are using Rebetron Combination Therapy, ask your partner to tell her doctor immediately.

Tell your doctor immediately if you become depressed or have suicidal feelings while you are using Rebetron Combination Therapy

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 in combination with Intron A. 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 having Rebetol in combination with Intron A.

Things you must not do

If you become drowsy from this therapy, do not drive or use machinery. Rebetron Combination Therapy may cause dizziness and drowsiness in some people.

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 switch to any other brands of interferon as your response to other interferons may be different.

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

Things to be careful of

Rebetron Combination Therapy can cause a temporary lowering of the number of cells/platelets in your blood

Check with your doctor about drinking alcoholic beverages or taking sleeping pills, sedatives or strong pain-killers.

Your doctor may want you to drink extra fluids. This will help prevent low blood pressure while you are using Rebetron Combination Therapy.

Check with your doctor immediately if you think you are getting a cold or chest infection. While using Rebetron Combination Therapy, you may temporarily have a greater risk of getting an infection.

Check with your doctor immediately 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
- you are looking unusually pale

If you are also taking antiviral medications (e.g. didanosine or abacavir) 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 serious condition known as "lactic acidosis" (high acid levels in the blood). This condition has been reported with some HIV (antiviral) medications.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Rebetron 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 Rebetron 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
- 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:

- injection site irritation, inflammation or pain
- flu-like symptoms such as headache, fatigue, fever and chills
- weakness, sleepiness
- flushing, increased sweating, feeling faint or dizziness
- shaky hands
- weight loss, loss of appetite
- stomach pain, indigestion or constipation
- feeling sick, vomiting or diarrhoea/intestinal gas
- muscular ache and pain, joint pain
- increased or decreased sensitivity to touch.
- sore mouth or tongue, dry mouth or taste change
- dry or teary eyes
- bleeding gums
- thirst
- 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

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 Rebetrone Combination Therapy, even if you do not think the problems are connected with the medicine.

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

After using Rebetol

Storage

Keep the Rebetol where children cannot reach.

Store the Rebetol capsules at room temperature (below 25°C). Do not leave it in the car.

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

A locked cupboard at least one 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 and "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.

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 New Zealand:

Schering-Plough a division of Schering-Plough Animal Health Limited

36 Kitchener Street

Auckland

NEW ZEALAND

Date of Preparation

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