

102210 revised Med Guide sent to the sponsor

MEDICATION GUIDE

REBETOL® (REB-eh-tol)

(ribavirin)

Capsules and Oral Solution

Read this Medication Guide before you start taking REBETOL, and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about REBETOL®?

1. **Do Not take REBETOL alone to treat chronic hepatitis C infection.** REBETOL should be used in combination with **either interferon alfa-2b (Intron A) or peginterferon alfa-2b (PegIntron)** to treat chronic hepatitis C infection.
2. **REBETOL may cause a significant drop in your red blood cell count and cause anemia in some cases. Anemia has been associated with worsening of Heart Problems, and in rare cases can cause a Heart Attack and Death.** Tell your healthcare provider if you have ever had any heart problems. REBETOL may not be right for you. **Seek medical attention right away if you experience chest pain.**
3. **REBETOL may cause Birth Defects or Death of your unborn baby. Do Not Take REBETOL if you or your sexual partner is pregnant or plan to become pregnant. Do Not become Pregnant within 6 months after discontinuing REBETOL therapy.** You must use 2 forms of birth control when you take REBETOL and for the 6 months after treatment.
 - Females must have a pregnancy test before starting REBETOL, every month while taking REBETOL, and every month for the 6 months after the last dose of REBETOL.
 - **If you or your female sexual partner becomes pregnant while taking REBETOL, tell your healthcare provider right away. You or your healthcare provider should contact the REBETOL pregnancy registry by calling 1-800-593-2214. The REBETOL pregnancy registry collects information about what happens to mothers and their babies if the mother takes REBETOL while she is pregnant.**

What is REBETOL?

REBETOL is a medicine used with either interferon alfa-2b (Intron A) or peginterferon alfa-2b (PegIntron) to treat chronic (lasting a long time) hepatitis C infection in people 3 years and older with liver disease.

It is not known if REBETOL use for longer than one year is safe and will work.

It is not known if REBETOL use in children younger than 3 years old is safe and will work.

Who should not take REBETOL?

See “What is the most important information I should know about REBETOL?”

Do not take REBETOL if you have:

- or ever had serious allergic reactions to the ingredients in REBETOL. See the end of this Medication Guide for a complete list of ingredients.
- certain types of hepatitis (autoimmune hepatitis).
- certain blood disorders (hemoglobinopathies).
- severe kidney disease.
- take didanosine (VIDEX®).

Talk to your healthcare provider before taking REBETOL if you have any of these conditions.

What should I tell my healthcare provider before taking REBETOL?

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Before you take REBETOL, tell your healthcare provider if you have or ever had:

- treatment for hepatitis C that did not work for you.
- breathing problems. REBETOL may cause or worsen breathing problems you already have.
- vision problems. REBETOL may cause eye problems or worsen eye problems you already have. You should have an eye exam before you start treatment with REBETOL.
- certain blood disorders such as anemia (low red blood cell count).
- high blood pressure, heart problems, or have had a heart attack. Your healthcare provider should check your blood and heart before you start treatment with REBETOL.
- thyroid problems
- liver problems other than hepatitis C infection
- human immunodeficiency virus (HIV) or any immunity problems
- mental health problems, including depression or thoughts of suicide
- kidney problems
- an organ transplant
- diabetes. REBETOL may make your diabetes worse or harder to treat.
- any other medical condition
- are breast feeding. It is not known if REBETOL passes into your breast milk. You and your healthcare provider should decide if you will take REBETOL or breast feed.

Tell your healthcare provider about all the medicines you take, including prescription medicines, vitamins, and herbal supplements. REBETOL may affect the way other medicines work.

Especially tell your healthcare provider if you take didanosine (VIDEX) or azathioprine (Imuran and Azasan).

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take REBETOL?

- Take REBETOL exactly as your healthcare provider tells you. Your healthcare provider will tell you the how much REBETOL to take and when to take it.
- Take REBETOL with food.
- Take **REBETOL Capsules** whole. Do not open, break, or crush **REBETOL Capsules** before swallowing. If you cannot swallow **REBETOL Capsules** whole, tell your healthcare provider.
- If you miss a dose of REBETOL, take the missed dose as soon as possible during the same day. Do not double the next dose. If you have questions about what to do, call your healthcare provider.
- If you take too much REBETOL, call your healthcare provider or Poison Control Center at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What are the possible side effects of REBETOL?

REBETOL may cause serious side effects, including:

See “What is the most important information I should know about REBETOL?”

- **Swelling and irritation of your pancreas (pancreatitis).** You may have stomach pain, nausea, vomiting, or diarrhea.
- **Serious breathing problems.** Difficulty breathing may be a sign of a serious lung infection (pneumonia) that can lead to death.

- **Serious eye problems** that may lead to vision loss or blindness.
- **Dental problems.** Your mouth may be very dry, which can lead to problems with your teeth and gums.
- **Severe depression**
- **Suicidal thoughts and attempts.** Adults and children who take REBETOL, especially teenagers are more likely to have suicidal thoughts or attempt to hurt themselves while taking REBETOL. Call your healthcare provider right away or go to the nearest hospital emergency room if you have new or worse depression or thoughts about suicide or dying.
- **Severe blood disorders.** An increased risk when used in combination with pegylated alpha interferons and azathioprine
- **Weight loss and slowed growth in children**

Tell your provider right away if you have any side effect that bothers you or that does not go away.

The most common side effects of REBETOL include:

- flu-like symptoms - feeling tired, headache, shaking along with high temperature (fever), nausea, and muscle aches.
- mood changes, feeling irritable.

The most common side effects of REBETOL in children include:

- a decrease in the blood cells that fight infection (neutropenia).
- a decrease in appetite.
- stomach pain and vomiting.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of REBETOL. For more information ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store REBETOL?

- Store **REBETOL Capsules** between 59°F to 86°F (15°C to 30°C).
- Store **REBETOL Oral Solution** between 59°F to 86°F (15°C to 30°C) or in the refrigerator between 36°F to 46°F (2°C to 8°C).

Keep REBETOL and all medicines out of the reach of children.

GENERAL INFORMATION ABOUT THE SAFE AND EFFECTIVE USE OF REBETOL.

It is not known if treatment with REBETOL will cure hepatitis C virus infections or prevent cirrhosis, liver failure, or liver cancer that can be caused by hepatitis C virus infections. It is not known if taking REBETOL will prevent you from infecting another person with the hepatitis C virus.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use REBETOL for a condition for which it was not prescribed. Do not give REBETOL to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about REBETOL. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or health care provider for information about REBETOL that is written for health professionals.

What are the ingredients in REBETOL?

Active ingredients: ribavirin

REBETOL Capsules

Inactive ingredients: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, and

magnesium stearate. The capsule shell consists of gelatin, sodium lauryl sulfate, silicon dioxide, and titanium dioxide. The capsule is printed with edible blue pharmaceutical ink which is made of shellac, anhydrous ethyl alcohol, isopropyl alcohol, n-butyl alcohol, propylene glycol, ammonium hydroxide, and FD&C Blue #2 aluminum lake.

REBETOL Oral Solution

Inactive ingredients: sucrose, glycerin, sorbitol, propylene glycol, sodium citrate, citric acid, sodium benzoate, natural and artificial flavor for bubble gum # 15864, and water.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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