

**120307.final draft Med Guide**

**MEDICATION GUIDE**

**REBETOL<sup>®</sup> (ribavirin, USP) Capsules and Oral Solution**

Read this medication guide carefully before you or your child begin taking REBETOL<sup>®</sup> [REB-eh-tol] Capsules or Oral Solution, and each time you refill your prescription in case new information has been included. This summary does not tell you everything about REBETOL Capsules or Oral Solution. Your health care provider is the best source of information about this medicine. After reading this medication guide, talk with your health care provider if you have any questions about REBETOL.

**WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT THERAPY WITH REBETOL CAPSULES OR ORAL SOLUTION?**

- **REBETOL Capsules and Oral Solution may cause birth defects or death of an unborn child. Therefore, if you are pregnant or your sexual partner is pregnant, do not take REBETOL.** If you could become pregnant, you must not become pregnant during therapy and for 6 months after you have stopped therapy. During this time you must use 2 forms of birth control, and you must have pregnancy tests that show that you are not pregnant.

Female sexual partners of male patients being treated with REBETOL must not become pregnant during treatment and for 6 months after treatment has stopped. Therefore, you must use 2 forms of birth control during this time.

If you or a female sexual partner becomes pregnant, you should tell your health care provider. There is a Ribavirin Pregnancy Registry that collects information about pregnancy outcomes in female patients and female partners of male patients exposed to ribavirin. You or your health care provider are encouraged to contact the Registry at 1-800-593-2214.

Be assured that any information you tell the Registry will be kept confidential. (See “**What should I avoid while taking REBETOL Capsules and Oral Solution?**”)

- After each use of REBETOL Oral Solution, wash the measuring cup or spoon to avoid swallowing of the medicine by someone other than the person to whom it was prescribed.
- **REBETOL Capsules and Oral Solution can cause a dangerous drop in your red blood cell count.**

REBETOL Capsules and Oral Solution can cause anemia, which is a decrease in the number of red blood cells. This can be dangerous, especially if you have heart or breathing problems. Tell your health care provider before taking REBETOL if you have ever had any of these problems. Your health care provider should check your red blood cell count before you start therapy and often during the first 4 weeks of therapy. Your red blood cell count may be checked more often if you have any heart or breathing problems.

- **Do not take REBETOL Capsules or Oral Solution alone to treat hepatitis C infection.** REBETOL Capsules should be used in combination with interferon alfa-2b (INTRON A) or in

combination with peginterferon alfa-2b (PegIntron) for treating chronic hepatitis C infection in adults. In children, safety and effectiveness of REBETOL Capsules or Oral Solution has only been shown when used in combination with interferon alfa-2b (INTRON A). Your health care provider or pharmacist should give you a copy of the INTRON A or PegIntron Medication Guide. They have additional important information about combination therapy not covered in this guide.

### **What is REBETOL (ribavirin)?**

“REBETOL” is a form of the antiviral drug ribavirin. It is used in combination with interferon alfa-2b to treat some patients with chronic hepatitis C infection. It is not known how REBETOL and interferon alfa-2b work together to fight hepatitis C infection (see the INTRON A or PegIntron Medication Guide).

It is not known if treatment with REBETOL and interferon alfa-2b 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 treatment with REBETOL and interferon alfa-2b will prevent an infected person from infecting another person with the hepatitis C virus.

### **Who should not take REBETOL Capsules or Oral Solution?**

#### **Do not use these medicines if:**

- You are a female and you are pregnant or plan to become pregnant at any time during your treatment with REBETOL or during the 6 months after your treatment has ended.
- You are a male patient with a female sexual partner who is pregnant or plans to become pregnant at any time while you are being treated with REBETOL or during the 6 months after your treatment has ended. (See “**What is the most important information I should know about therapy with REBETOL Capsules or Oral Solution?**” and “**What should I avoid while taking REBETOL Capsules or Oral Solution?**”)
- You are breast-feeding. REBETOL may pass through your milk and harm your baby. Talk with your provider about whether you should stop breast-feeding.
- You are allergic to any of the ingredients in REBETOL Capsules or Oral Solution. See the ingredients listed at the end of this Medication Guide.

#### **Tell your health care provider before starting treatment with REBETOL Capsules or Oral Solution in combination with PegIntron/INTRON A if you have any of the following medical conditions:**

- **mental health problems, such as depression or anxiety.** REBETOL/PegIntron/INTRON A therapy may make them worse. Tell your health care provider if you are being treated or had treatment in the past for any mental problems, including depression, suicidal behavior, or a feeling of loss of contact with reality, such as hearing voices or seeing things that are not there (psychosis). Tell your health care provider if you take any medicines for these problems.
- **high blood pressure, heart problems, or have had a heart attack.** REBETOL Capsules and Oral Solution may worsen heart problems. Patients who have had certain heart problems should not take REBETOL Capsules or Oral Solution.
- **blood disorders,** including anemia (low red blood cell count), thalassemia (Mediterranean anemia), and sickle-cell anemia. REBETOL Capsules and Oral Solution can reduce the number of

red blood cells you have. This may make you feel dizzy or weak and could worsen any heart problems you might have.

- **kidney problems.** If your kidneys do not work properly, you may experience worse side effects from REBETOL therapy and require a lower dose.
- **liver problems** (other than hepatitis C infection)
- **organ transplant**, and are taking medicine that keeps your body from rejecting your transplant (suppresses your immune system).
- **thyroid disease.** REBETOL/PegIntron/INTRON A therapy may make your thyroid disease worse or harder to treat. REBETOL/PegIntron/INTRON A therapy may be stopped if you develop thyroid problems that cannot be controlled by medicine.
- **lung problems.** REBETOL/PegIntron/INTRON A therapy can cause breathing problems or worsen breathing problems you already have.
- **alcoholism or drug abuse or addiction**
- **cancer**
- **infection with hepatitis B virus and/or human immunodeficiency virus** (the virus that causes AIDS).
- **diabetes.** REBETOL/PegIntron/INTRON A therapy may make your diabetes worse or harder to treat.
- **past interferon treatment for hepatitis C virus infection that did not work for you.**

**For more information see the INTRON A or PegIntron Medication Guides.**

### **How should I take REBETOL Capsules or Oral Solution?**

Your health care provider has determined the correct dose of REBETOL Capsules or Oral Solution based on your weight. Your health care provider may lower your dose of REBETOL if you have side effects.

- It is important to follow your dosing schedule and your health care provider's instructions on how to take your medicines.
- Under no circumstances should REBETOL Capsules be opened, crushed, or broken.
- You should take REBETOL with food. Taking REBETOL with food helps your body take up more of the medicine. Taking REBETOL at the same time of day every day will help keep the amount of medicine in your body at steady level. This can help your health care provider decide how your treatment is working and how to change the number of REBETOL capsules you take if you have side effects.
- Take the medicine for as long as prescribed and do not take more than the recommended dose.
- If you miss a dose of REBETOL Capsules or Oral Solution, take the missed dose as soon as possible during the same day. If an entire day has gone by, check with your health care provider about what to do. Do not double the next dose.
- Tell your health care provider if you are taking or planning to take other prescription or non-prescription medicines, including vitamin and mineral supplements, and herbal medicines.
- Tell your provider before taking REBETOL Capsules or Oral Solution if you have ever had any heart or breathing problems. Your provider should check your red blood cell count before starting therapy and often during the first 4 weeks of therapy. Your red blood cell count may be checked more frequently if you have had heart or breathing problems.

- Females taking REBETOL Capsules or Oral Solution or female sexual partners of male patients taking REBETOL Capsules or Oral Solution must have a pregnancy test before treatment begins, every month during treatment, and for 6 months after treatment ends to make sure there is no pregnancy.

### **What should I avoid while taking REBETOL Capsules or Oral Solution?**

Avoid the following during REBETOL Capsule or Oral Solution treatment:

- **Pregnancy:** If you or your sexual partner gets pregnant during treatment with REBETOL Capsules or Oral Solution or in the 6 months after treatment ends, tell your health care provider right away. (See “**What is the most important information I should know about therapy with REBETOL Capsules or Oral Solution?**”)

Talk with your health care provider about how to avoid pregnancy. If you or your sexual partner gets pregnant while on REBETOL or during the 6 months after your treatment ends, you must report the pregnancy to your health care provider right away. Your health care provider should call 1-800-593-2214. Your health care provider will be asked to give follow-up information about the pregnancy. Any information about your pregnancy that is reported about you will be confidential.

- **Breastfeeding.** The medicine may pass through your milk and harm the baby.
- **Drinking alcohol,** including beer, wine, and liquor. This may make your liver disease worse.
- **Taking other medicines.** Take only medicines prescribed or approved by your health care provider. These include prescription and nonprescription medicines and herbal supplements.

### **What are the most common side effect of REBETOL Capsules and Oral Solution?**

**The most serious possible side effects of REBETOL Capsules and Oral Solution are:**

**Harm to unborn children.** REBETOL Capsules and Oral Solution may cause birth defects or death of an unborn child. (For more details, see “What is the most important information I should know about REBETOL Capsules or Oral Solution?”)

- **ANEMIA.** Anemia is a reduction in the number of red blood cells you have which can be dangerous, especially if you have heart or breathing problems. Tell your healthcare provider right away if you feel tired, have chest pain or shortness of breath. These may be signs of low red blood cell counts.

**Tell your provider right away if you have any of the following symptoms. They may be signs of a serious effect:**

- **trouble breathing**
- **hives or swelling**
- **chest pain**
- **severe stomach or low back pain**
- **bloody diarrhea or bloody stools (bowel movements). These may appear black and tarry.**
- **bruising**
- **other bleeding**

**The most common side effects of REBETOL Capsules and Oral Solution are:**

- **feeling tired**
- **nausea and appetite loss**
- **rash and itching**
- **cough**

This summary does not include all possible side effects of REBETOL therapy. Talk to your health care provider if you do not feel well while taking REBETOL. Your health care provider can give you more information about managing your side effects.

### **What should I know about hepatitis C infection?**

Hepatitis C infection is a disease caused by a virus that infects the liver. This liver infection becomes a continuing (chronic) condition in most patients. Patients with chronic hepatitis C infection may develop cirrhosis, liver cancer, and liver failure. The virus is spread from one person to another by contact with the infected person's blood. You should talk to your health care provider about ways to prevent you from infecting others.

### **How do I store my REBETOL Capsules?**

Store REBETOL Capsules at room temperature 77°F (25°C).

### **How do I store my REBETOL Oral Solution?**

Store REBETOL Oral Solution at room temperature 77°F (25°C) or in the refrigerator 36° to 46°F (2° to 8°C).

### **General advice about prescription medicines**

Do not use REBETOL Capsules or Oral Solution for conditions for which they were not prescribed. If you have any concern about REBETOL Capsules or Oral Solution, ask your health care provider. Your health care provider or pharmacist can give you information about REBETOL Capsules or Oral Solution that was written for health care professionals. Do not give this medicine to other people, even if they have the same condition you have.

### **Ingredients:**

REBETOL Capsules contain ribavirin and the inactive ingredients microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, and magnesium stearate. The capsule shell consists of gelatin 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 contains ribavirin and the inactive ingredients sodium citrate, citric acid, sodium benzoate, glycerin, sucrose, sorbitol, propylene glycol, and water.

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

Manufactured by:

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