


Drug Information Sheet ("Kusuri-no-Shiori")

610451031

Revised: 09/2011

<p>Information is based on approvals granted in Japan. In some cases, the approved details may vary in countries other than Japan. In deciding to use a medicine, the risk (side effects) of taking the medicine must be weighed against the benefit (effects) it will do. The patient's cooperation is indispensable here.</p>	
<p>Brand name : REBETOL capsules 200mg Active ingredient : Ribavirin Dosage form : white hard gelatin capsule(length: 19.2mm) Printings on wrapping : (front side) 921, (back side) レベトール 200mg 921</p>	
<p>Effects of this medicine This medicine is used with interferon (Interferon alpha-2b, Peginterferon alpha-2b or Interferon beta) and other antiviral agents to inhibit the growth of hepatitis C virus. It also helps eliminating the virus from your body so that to improve the liver functioning. It is usually used to treat chronic hepatitis C.</p>	
<p>Before using this medicine, tell your doctor/pharmacist</p> <ul style="list-style-type: none"> • If you ever experienced any allergic reaction (itch, rash etc.) to any medicine. If you are patient with heart disease (myocardial infarction, heart failure, arrhythmia), abnormal hemoglobin disease (thalassemia, drepanocytic anemia), kidney/liver disorder, autoimmune hepatitis, mental illness or with history of it. • If you are pregnant or breastfeeding. • If you are using any other prescription or nonprescription (OTC) medicine. (It is important to reduce the risk of drug interactions.) 	
<p>Dosage regimen (proper use of this medicine)</p> <ul style="list-style-type: none"> • Your dosage regimen is:◀◀ :order of your doctor▶▶ • General dosage regimen: For adults, take this medicine according to your body weight after meals. If you weigh 60kg and below, take 3 capsules (600mg) a day [1capsule (200mg) after breakfast and 2 capsules (400mg) after dinner]. If your weight ranges over 60kg to 80kg, take 4 capsules (800mg) a day [2 capsules (400mg) after breakfast and 2 capsules (400mg) after dinner]. If you weigh over 80kg, take 5 capsules (1,000mg) a day [2 capsules (400mg) after breakfast and 3 capsules (600mg) after dinner]. The dosage should be reduced or this medicine should be discontinued according to your age and symptoms. Strictly follow the instructions of your doctor/pharmacist. • Missed dose: If you are ordered to use this medicine on regular schedule and you missed a dose, check with your doctor/pharmacist. DO NOT take double doses to make up for the missed dose. • Overdose: If you took too much of the medicine (more than ordered), check with your doctor/pharmacist. • Others: Do not stop taking the medicine without the instructions of your doctor. 	
<p>Precautions while using this medicine</p> <ul style="list-style-type: none"> • Female patient who may possibly become pregnant must have a pregnancy test each month during the drug therapy and for 6 months afterward in order to make sure you are not pregnant. Male patients: If your partner is pregnant or possibly become pregnant, wear condoms during the drug therapy and for 6 months afterward in order to prevent transporting semen into the uterus. Follow your doctor's instructions and take periodical blood tests. 	

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Side effects of this medicine

Common side effects are reported as below. If any of them occurs, check with your doctor/pharmacist: fever, lassitude, headache, top-heavy feeling, chills, sleeplessness, loss of appetite, vomiting, nausea, joint pain, muscle pain, abdominal pain, eye floater (view of flying mosquito), visual degradation, etc.

In rare cases, symptoms described below may be the sign of side effects indicated in brackets []. If they occur, stop taking your medicine and check with your doctor immediately.

- palpitation when going upstairs or uphill, shortness of breath, dizziness [anemia]
- sore throat, muscle pain, feeling of serious illness, high fever with chills [agranulocytosis, leukopenia, thrombocytopenia]
- sleeplessness, anxiety, irritation [depression, suicide attempt, aggressive behavior]
- facial pallor, shortness of breath, dizziness on standing up [shock]
- dry cough, breathing difficulty, general malaise [interstitial pneumonia, pulmonary fibrosis, pulmonary edema]

Other side effects not listed here may occur. Check with your doctor/pharmacist if you have any worrisome symptom.

Storage and other information

- Keep out of the reach of children. Store at room temperature (1-30°C), away from direct sunlight and moisture.
- Discard the remainder. Do not store them. Ask the pharmacist how to discard.

For doctor use only: Day Month Year

For further information, ask your doctor/pharmacist. Japanese package insert information (for medical professionals) is available on the website of Pharmaceuticals and Medical Devices Agency.