

Celbarin®

Ribavirin BP 200 mg capsule

Presentation: Celbarin® Each capsule contains Ribavirin BP 200 mg

Description: Ribavirin is a nucleoside analog with antiviral activity.

Indication and uses: Ribavirin BP is indicated in combination with peg-interferon alpha-2a, 2b or interferon alpha injection for the treatment of chronic hepatitis C in patients with compensated liver disease previously untreated with alpha interferon or who have relapsed following alpha interferon therapy. Patients in whom efficacy was demonstrated included patients with compensated liver disease and histological evidence of cirrhosis.

Dosage and administration: The recommended duration of treatment for patients previously untreated with interferon is 24 to 48 weeks. After 24 weeks of treatment virologic response should be assessed. Treatment discontinuation should be considered in any patient who has not achieved an HCV RNA below the limit of detection of the assay by 24 weeks. There are no safety and efficacy data on treatment for longer than 48 weeks in the previously untreated patient population. In patients who relapse following interferon therapy, the recommended duration of treatment is 24 weeks. There are no safety and efficacy data on treatment for longer than 24 weeks in the relapse patient populations.

Ribavirin + Interferon			
Genotype	Ribavirin Daily	Interferon alpha-2a or interferon alpha-2b	Duration
All Genotypes	≤ 75 kg=(400+600) mg	3 MIU 3 times weekly subcutaneously	48 weeks (Genotype1&4)
	> 75 kg=(600+600) mg		24 weeks (Genotype2&3)

Ribavirin + Peg-Interferon			
Genotype	Ribavirin Daily	Peg-Interferon alpha-2a or Peg-interferon alpha-2b	Duration
1 & 4	< 75 kg=(400+600) mg > 75 kg=(600+600) mg	180 µgm once weekly subcutaneously	48 weeks
2 & 3	(400+400) mg		24 weeks

Ribavirin may be administered without regard to food, but should be administered in a consistent manner. Drink plenty of water while being treated with this medication; drinking water will decrease the risk of serious side effects.

Side effects: Nausea, vomiting, headache, dizziness, blurred vision, stomach upset, trouble sleeping, and flu-like symptoms (e.g. fever, chills, sore throat, muscle aches) may occur. Other severe side effects include hair loss, loss of appetite, weight loss, rash, itching, fatigue, dark urine, yellowing of eyes, mood changes (including severe depression or suicidal thoughts), trouble breathing, chest pain, muscle pain, joint pain, rapid breathing, stomach pain, easy bruising or unusual bleeding.

Contraindications: Ribavirin is contraindicated in patients with known hypersensitivity to Ribavirin or any components of the capsule, women who are pregnant, men whose female partners are pregnant, patients with hemoglobinopathies (e.g. thalassemia major or sickle cell anemia), autoimmune hepatitis or hepatic decompensation before or during treatment. No pharmacokinetic interactions were noted between peg-interferon alpha and Ribavirin.

Precautions: Before using this medicine, consult your doctor if you have: severe heart disease, kidney disease, blood disorders (e.g. sickle cell anemia, low hemoglobin), other types of hepatitis (e.g. autoimmune hepatitis), other liver problems, heart problems, breathing problems, pancreas problems (e.g. pancreatitis), diabetes, any allergies. Use caution engaging in activities requiring alertness such as driving or using machinery. Caution is advised when using this drug in the elderly because they may be more sensitive to its effects.

Pregnancy and lactation: This medication must not be used during pregnancy. It is not known whether this drug passes into breast milk. Because of the potential risk to the infant, breast-feeding while using this drug is not recommended.

Pediatric patients: Safety and efficacy of Ribavirin has not been established in patients below the age of 18 yrs.

Drug interactions: This drug should not be used with the following medications because very serious interactions may occur: Didanosine, Stavudine, Zidovudine.

Missed dose: If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

Storage conditions: Ribavirin capsules should be stored at 25°C; away from light and moisture. Brief storage between 15-30° C is permitted. Keep all medicines away from children.

Commercial Pack: Celbarin® Each box contains 2 blister strips of 10 capsules.

Manufactured by



Incepta Pharmaceuticals Ltd.

Dhaka, Bangladesh

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