

Ribacee™

Ribavirin

Composition:

Ribacee™ Capsule: Each capsule contains Ribavirin USP 200 mg.

Description:

Ribacee™ (Ribavirin) is an antiviral agent. Ribavirin is a synthetic nucleoside analogue (purine analogue). The chemical name of Ribavirin is 1-D-ribofuranosyl-1H-1,2,4-triazole-3-carboxamide. The mechanism by which Ribavirin contributes to its antiviral efficacy in the clinic is not fully understood. Ribavirin has direct antiviral activity in tissue culture against many RNA viruses. Ribavirin increases the mutation frequency in the genomes of several viruses and Ribavirin triphosphate inhibits HCV polymerase in a biochemical reaction.

Indications:

Ribacee™ in combination with Interferon alpha-2b (pegylated and nonpegylated) or sofosbuvir is indicated for the treatment of Chronic Hepatitis.

The following points should be considered when initiating Ribavirin combination therapy with Sofosbuvir or Interferon alpha.

Combination therapy with Ribavirin & Sofosbuvir is preferred over Ribavirin & Interferon as this combination provides substantially better response rates.

No safety and efficacy data are available for treatment of longer than one year.

Dosage & Administration:

Ribacee™ should be taken with food. In patients who relapse following nonpegylated Interferon monotherapy, the recommended duration of treatment is 24 weeks.

Recommended combination therapy: (HCV Mono-infected and HCV/HIV-1 Co-infected)

Genotype 1 or 4 : Sofosbuvir + Peginterferon alpha + Ribavirin for 12 weeks

Genotype 2 : Sofosbuvir + Ribavirin for 12 weeks

Genotype 3 : Sofosbuvir + Ribavirin for 24 weeks

Recommended Dosing for Ribavirin in Combination Therapy:

Body Weight (kg)	Ribavirin Daily Dose	Ribacee™ Number of Capsules
47-65	800 mg/day	2 x 200 mg capsules AM 2 x 200 mg capsules PM
66-80	1000 mg/day	2 x 200 mg capsules AM 3 x 200 mg capsules PM
81-105	1200 mg/day	3 x 200 mg capsules AM 3 x 200 mg capsules PM
>105	1400 mg/day	3 x 200 mg capsules AM 4 x 200 mg capsules PM

OR AS DIRECTED BY THE PHYSICIAN.

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, rash, itching, fatigue, dark urine, yellowing of eyes, mood of changes (including severe depression or suicidal thoughts), trouble breathing, chest pain, muscle pain, joint pain, rapid breathing, stomach pain, easy bruising or unusual bleeding.

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.

Use in Pregnancy & 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.

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

Organ transplant recipients: Safety and efficacy not studied.

Co-infected Patients: Safety and efficacy with HIV or HBV co-infection have not been established

Drug Interaction:

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

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 Peginterferon alpha and Ribavirin.

Storage Condition:

Keep in a cool and dry place below 30° C, protect from light. Keep out of the reach of children.

Presentation:

Ribacee™ Capsule: Each box contains 1x10's/3x10's capsules in Alu-Alu blister pack.

Manufactured by:

Julphar Bangladesh Ltd.

Sreepur, Gazipur, Bangladesh.