



Prior Authorization Approval Criteria

ribavirin

Generic name: Ribavirin

Brand names: Copegus, Rebetol, Ribasphere

Medication class: Antiviral

FDA-approved uses: Treatment of hepatitis C in combination with peginterferon alfa-2b, interferon alpha-2a or interferon alpha-2b. Should not be used as monotherapy for this indication.

Usual dose range: *Copegus:* For genotypes 2 and 3, 800 mg/day in 2 divided doses. For genotypes 1 and 4, 1200 mg/day in 2 divided doses.
Ribasphere: 800 mg/day in 2 divided doses.
Rebetol adult dosing:*

Body weight	Rebetol capsules
≤ 75 kg	2 × 200 mg capsules AM, 3 × 200 mg capsules PM daily p.o.
> 75 kg	3 × 200 mg capsules AM, 3 × 200 mg capsules PM daily p.o.

Rebetol pediatric dosing:*

Body weight	Rebetol capsules	Interferon alfa-2b injection
25-36 kg	1 × 200 mg capsules AM, 1 × 200 mg capsules PM daily p.o.	3 million IU/m ² 3 times weekly s.c.
37-49 kg	1 × 200 mg capsules AM, 2 × 200 mg capsules PM daily p.o.	3 million IU/m ² 3 times weekly s.c.
50-61 kg	2 × 200 mg capsules AM, 2 × 200 mg capsules PM daily p.o.	3 million IU/m ² 3 times weekly s.c.

The recommended dose of Rebetol oral solution is 15 mg/kg per day orally (divided dose AM and PM). Rebetol oral solution is supplied in a concentration of 40 mg/mL.

Duration of therapy: 24 weeks for genotypes 2 and 3; 48 weeks for genotypes 1 and 4

Criteria for use (bullet points below are all inclusive unless otherwise noted):

- Clinically diagnosed hepatitis C with detectable HCV RNA levels
- Have not been previously treated with interferon alpha.
- Must be used in combination with peginterferon alfa-2a or interferon alpha-2b.
- Liver biopsy, unless contraindicated, shows fibrosis and inflammatory necrosis.
- If patient meets criteria, FCHP will only approve ribavirin 200 mg tablets or capsules. Other dosage forms (i.e., Ribapak) may be approved if the patient has an inability (other than non-compliance) to use 200 mg tablets/capsules.

*** Criteria for pediatric use of Rebetol capsules:**

- Clinically diagnosed hepatitis C
- Compensated liver disease previously untreated with alpha interferon
- Relapsed following alpha interferon therapy
- Must be used in combination with interferon alfa-2b for injection
- Must be 5 years of age or older

*** Criteria for pediatric use of Rebetol solution:**

- Clinically diagnosed hepatitis C
- compensated liver disease previously untreated with alpha interferon
- relapsed following alpha interferon therapy
- Must be used in combination with interferon alfa-2b for injection
- Must be 3 years of age or older

Guidelines for continuation of therapy for an additional 24 weeks:

- Patient must have HCV genotype 1 or 4
- After 24 weeks, the patient has undetectable HCV RNA levels
- Must provide patient's most recent CBC, including HCT and HGB

Contraindications:

- Hypersensitivity to ribavirin or any components of the tablet
- Women who are pregnant
- Men whose female partners are pregnant
- Patients with hemoglobinopathies
- Patients with a history of significant or unstable cardiac disease
- Creatinine clearance < 50ml/min

Ribavirin and peginterferon alfa-2a combination is contraindicated in patients with:

- Autoimmune hepatitis
- Hepatic decompensation

Not approved if:

- Patient has any contraindications to the use of ribavirin.
- Patient does not meet the above-stated guidelines for approval.

Guidelines for dose modification and discontinuation of interferon/ribavirin for hematologic toxicity:

Laboratory values	Peginterferon alfa-2b	Ribavirin
HGB**		
< 10.0 g/dL	-----	Decrease by 200 mg/day
< 8.5 g/dL	Permanently discontinue	Permanently discontinue
WBC		
< 1.5 x 10 ⁹ /L	Reduce dose by 50%	-----
< 1.0 x 10 ⁹ /L	Permanently discontinue	Permanently discontinue
Neutrophils		
< 0.75 x 10 ⁹ /L	Reduce dose by 50%	-----
< 0.5 x 10 ⁹ /L	Permanently discontinue	Permanently discontinue
Platelets		
< 80 x 10 ⁹ /L	Reduce dose by 50%	-----
< 50 x 10 ⁹ /L	Permanently discontinue	Permanently discontinue

**** For patients with a history of stable cardiac disease receiving peginterferon alfa-2b in combination with ribavirin, the peginterferon alfa-2b dose should be reduced by half and the ribavirin dose by 200 mg/day if a >2 g/dL decrease in hemoglobin is observed during any 4 week period. Both peginterferon alfa-2b and ribavirin should be permanently discontinued if patients have hemoglobin levels <12 g/dL after this ribavirin dose reduction.**

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 11/15/04
 First revision: 3/12/08
 Second revision: 09/03/08