



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: ribavirin

Brand Name: Copegus, Rebetol*, Ribasphere (generic Rebetol, AB rated), ribavirin

Medication Class: Antiviral

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

Usual Dose: Copegus: Genotypes 2 and 3- 800mg/ day in 2 divided doses.
Genotypes 1 and 4- 1200 mg/ day in 2 divided doses.
Ribasphere: 800mg/day in 2 divided doses
Rebetol:

Recommended Adult Dosing	
Body weight	REBETOL Capsules
<= 75 kg	2 x 200-mg capsules AM, 3 x 200-mg capsules PM daily p.o.
> 75 kg	3 x 200-mg capsules AM, 3 x 200-mg capsules PM daily p.o.

Recommended Pediatric Dosing		
Body weight	REBETOL Capsules	INTRON A Injection
25-36 kg	1 x 200-mg capsules AM, 1 x 200-mg capsules PM daily p.o.	3 million IU/m ² 3 times weekly s.c.
37-49 kg	1 x 200-mg capsules AM, 2 x 200-mg capsules PM daily p.o.	3 million IU/m ² 3 times weekly s.c.
50-61 kg	2 x 200-mg capsules AM, 2 x 200-mg capsules PM daily p.o.	3 million IU/m ² 3 times weekly s.c.



>61 kg	Refer to adult dosing table	Refer to adult dosing table
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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.

***Criteria for Pediatric Use for 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 Intron A for injection.
- Must be 5 years of age or older.

***Criteria for Pediatric Use for 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 Intron A 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	Ribavirin
Hgb*	<10.0 g/dl	-----	Decrease by 200 mg/day
	<8.5 g/dl	Permanently discontinue	Permanently discontinue
WBC	<1.5 x10 ⁹ /L	Reduce dose by 50%	-----
	<1.0 x10 ⁹ /L	Permanently discontinue	Permanently discontinue
Neutrophil x10 ⁹ /L	<0.75	Reduce dose by 50%	-----
	<0.5 x10 ⁹ /L	Permanently discontinue	Permanently discontinue
Platelets	<80 x10 ⁹ /L	Reduce dose by 50%	-----
	<50 x10 ⁹ /L	Permanently discontinue	Permanently discontinue

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

P&T Approval: _____ Date: _____