Ribavirin:

Class: Antiviral Agent.

Indications:

Inhalation: Treatment of hospitalized infants and young children with respiratory syncytial virus (RSV) infections; specially indicated for treatment of severe lower respiratory tract RSV infections in patients with an underlying compromising condition (prematurity, cardiopulmonary disease, or immunosuppression)

Oral capsule: In combination with interferon alfa 2b (pegylated or nonpegylated) injection for the treatment of chronic hepatitis C in interferon alfa-naive or experienced-patients with compensated liver disease. Patients likely to fail retreatment after a prior failed course include previous nonresponders, those who received previous pegylated interferon treatment, patients who have significant bridging fibrosis or cirrhosis, or those with genotype 1 infection.

Oral solution: In combination with interferon alfa-2b (pegylated or nonpegylated) injection for the treatment of chronic hepatitis C in interferon alfa-naive or experienced patients ≥3 years of age with compensated liver disease. Patients likely to fail retreatment after a prior failed course include previous nonresponders, those who received previous pegylated interferon treatment, patients who have significant bridging fibrosis or cirrhosis, or those with genotype 1 infection.

Oral tablet: In combination with peginterferon alfa-2a (Pegasys®) injection for the treatment of chronic hepatitis C in patients with compensated liver disease who were previously untreated with alpha interferons, and in adult chronic hepatitis C patients coinfected with HIV.

Available dosage form in the hospital: 200MG CAP.

Dosage:

-**Chronic hepatitis C monoinfection (in combination with peginterferon alfa-2b):** *Oral capsule, oral solution (Rebetol®, Ribasphere®):* **Note:** Recommended therapy duration [manufacturer labeling]: Genotype 1: 48 weeks; genotypes 2,3: 24 weeks); recommended therapy duration for patients who previously failed therapy: 48 weeks [regardless of genotype])

- ≤65 kg: 800 mg daily (400 mg in the morning and evening)
- 66-80 kg: 1000 mg daily (400 mg in the morning, 600 mg in the evening)
- 81-105 kg: 1200 mg daily (600 mg in the morning, 600 mg in the evening)
- >105 kg: 1400 mg daily (600 mg in the morning, 800 mg in the evening)

-**Chronic hepatitis C monoinfection (in combination with interferon alfa-2b):** *Oral capsule (Rebetol®, Ribasphere®):* **Note:** Individualized therapy duration [manufacturer labeling] 24-48 weeks):

- ≤75 kg: 1000 mg daily (400 mg in the morning, 600 mg in the evening)
- >75 kg: 1200 mg daily (600 mg in the morning, 600 mg in the evening)

-**Chronic hepatitis C monoinfection (in combination with peginterferon alfa-2a):** *Oral tablet (Copegus®, Ribasphere®):*

-Genotype 1,4:

- <75 kg: 1000 mg daily in 2 divided doses for 48 weeks
- ≥75 kg: 1200 mg daily in 2 divided doses for 48 weeks

-Genotype 2,3: 800 mg daily in 2 divided doses for 24 weeks

-**Chronic hepatitis C coinfection with HIV (in combination with peginterferon alfa-2a):** *Oral tablet (Copegus®, Ribasphere®):* 800 mg daily in 2 divided doses for 48 weeks (regardless of genotype)

- ***Alternative recommendation:*** *American Association for the Study of Liver Diseases (AASLD) guidelines:* Adults with chronic hepatitis C infection (Ghany, 2009): Treatment of choice: Ribavirin plus peginterferon; clinical condition and ability of patient to tolerate therapy should be evaluated to determine length and/or likely benefit of therapy. Recommended treatment duration (AASLD guidelines): Genotypes 1,4: 48 weeks; Genotypes 2,3: 24 weeks; Coinfection with HIV: 48 weeks.

-**RSV infection in hematopoietic cell or heart/lung transplant recipients (unlabeled use):** *Aerosol inhalation:* 2000 mg (over 2 hours) every 8 hours (Boeckh, 2007; Liu, 2010)

Note: Heart/lung transplant recipients also received IVIG, methylprednisolone and palivizumab. Dosage and protocol may be institution specific. (Boeckh, 2007; Chemaly, 2006; Liu, 2010).

Renal Impairment:

CHC infection: Oral:

-Rebetol® capsules/solution, Ribasphere® capsules: Adults:

-Cl_{cr} ≥50 mL/minute: No dosage adjustments are recommended.

-Cl_{cr} <50 mL/minute: Use is contraindicated.

-Ribasphere® tablets: Adults:

-Cl_{cr} ≥50 mL/minute: No dosage adjustments are recommended.

-Cl_{cr} <50 mL/minute: Use is not recommended.

-Copegus® tablets: Adults:

-Cl_{cr} >50 mL/minute: No dosage adjustments are recommended.

-Cl_{cr} 30-50 mL/minute: Alternate 200 mg and 400 mg every other day.

-Cl_{cr} <30 mL/minute: 200 mg once daily.

-ESRD requiring hemodialysis: 200 mg once daily

Adjustment for Toxicity:

-Patient **without** cardiac history:

-Hemoglobin <10 g/dL:

-Oral capsules, oral solution:

-First reduction: ≤105 kg: Decrease by 200 mg daily; >105 kg: Decrease by 400 mg daily

-Second reduction: Decrease by an additional 200 mg daily (not weight-based)

-Oral tablets: Decrease dose to 600 mg daily (200 mg in the morning, 400 mg in the evening)

-Hemoglobin <8.5 g/dL: Children and Adults: Oral capsules, solution, tablets: Permanently discontinue treatment.

-WBC <1000 mm^3, neutrophils <500 mm^3: Children and Adults: Oral capsules, solution: Permanently discontinue treatment.

-Platelets <50 x 10^9/L: Children: Oral capsules, solution: Permanently discontinue treatment.

-Platelets <25 x 10^9/L: Adults: Oral capsules, solution: Permanently discontinue treatment.

-Creatinine (serum) >2 mg/dL: Children: Oral capsules, solution: Permanently discontinue treatment.

-Patient **with** cardiac history:

-Hemoglobin has decreased >2 g/dL during any 4-week period of treatment: Adults:

-Oral capsules, solution: Decrease dose by 200 mg daily

-Oral tablets: 600 mg (200 mg in the morning, 400 mg in the evening)

-Hemoglobin <12 g/dL after 4 weeks of reduced dose: Children and Adults: Oral capsules, solution, tablets: Permanently discontinue treatment.

-Hemoglobin <8.5 g/dL: Children and Adults: Oral capsules, solution, tablets: Permanently discontinue treatment.

-WBC <1000 mm^3, neutrophils <500 mm^3: Children and Adults: Oral capsules, solution: Permanently discontinue treatment.

-Platelets <50 x 10^9/L: Children: Oral capsules, solution: Permanently discontinue treatment.

-Platelets <25 x 10^9/L: Adults: Oral capsules, solution: Permanently discontinue treatment.

-Creatinine (serum) >2 mg/dL at any time during therapy: Children: Oral capsules, solution: Permanently discontinue treatment.

Common side effect:

Inhalation:

Central nervous system: Fatigue, headache, insomnia

Gastrointestinal: Nausea, anorexia

Oral:

Central nervous system: Fatigue , headache , fever , insomnia ,dizziness

Dermatologic: Alopecia , pruritus,rash ,dry skin ,dermatitis .

Gastrointestinal: Nausea , anorexia , weight decrease , vomiting , diarrhea, abdominal pain .

Hematologic: Leukopenia , neutropenia , hemoglobin decreased

Neuromuscular & skeletal: Myalgia, arthralgia , musculoskeletal pain.

Pregnancy Risk Factor: X