*Only for the use of Medical Professionals*

# Chrocee®

Ribavirin

## Description

**Chrocee**® is a guanosine (ribonucleic) analog used to stop viral RNA synthesis and viral mRNA capping, thus, it is a nucleoside inhibitor. **Chrocee**® is a prodrug, which when metabolized resembles purine RNA nucleotides. In this form it interferes with RNA metabolism required for viral replication.

## Indications

**Chrocee**® in combination with peginterferon alfa-2a is indicated for the treatment of patients 5 years of age and older with chronic hepatitis C (CHC) virus infection who have compensated liver disease and have not been previously treated with interferon alpha.

## Dosage and administration

***Adult dose:***

| Hepatitis C Virus Genotype | Dose of PEG interferon alfa-2a | Dose of Chrocee® | Duration |
|---|---|---|---|
| Genotype 1, 4 | 180 mcg | <75 kg = 1000 mg | 48 weeks |
| | | ≥75 kg = 1200 mg | 48 weeks |
| Genotype 2, 3 | 180 mcg | 800 mg | 24 weeks |

***Pediatric dose:***

| Body Weight (kg) | Chrocee® Daily Dose* | Number of capsules |
|---|---|---|
| 23 – 33 | 400 mg/day | 1 x 200 mg capsule A.M.<br>1 x 200 mg capsule P.M. |
| 34 – 46 | 600 mg/day | 1 x 200 mg capsule A.M.<br>2 x 200 mg capsule P.M. |
| 47 – 59 | 800 mg/day | 2 x 200 mg capsule A.M.<br>2 x 200 mg capsule P.M. |
| 60 – 74 | 1,000 mg/day | 2 x 200 mg capsule A.M.<br>3 x 200 mg capsule P.M. |
| ≥75 | 1,200 mg/day | 3 x 200 mg capsule A.M.<br>3 x 200 mg capsule P.M. |

** Approximately 15 mg/kg/day*

**Use in pregnancy**

**Chrocee**® may cause birth defects and/or death of the exposed fetus. Ribavirin has demonstrated significant teratogenic and/or embryocidal effects in all animal species in which adequate studies have been conducted. These effects occurred at doses as low as one twentieth of the recommended human dose of Ribavirin. Ribavirin treatment should not be started until a report of a negative pregnancy test has been obtained immediately prior to initiation of therapy.

**Side effects**

The most common adverse reactions (frequency greater than 40%) in adults receiving combination therapy are fatigue/asthenia, pyrexia, myalgia, and headache.

**Precautions**

Renal impairment patients: Dose should be reduced in patients with creatinine clearance less than or equal to 50 mL/min.

**Drug interactions**

- Nucleoside analogues: Closely monitor for toxicities. Discontinue nucleoside reverse transcriptase inhibitors or reduce dose or discontinue Interferon, Ribavirin or both with worsening toxicities.
- Azathioprine: Concomitant use of Azathioprine with Ribavirin has been reported to induce severe pancytopenia and may increase the risk of Azathioprine-related myelotoxicity.

**Pharmaceutical precautions**

Store in a cool (below 30° C) and dry place. Protect from light.

**Presentation**

**Chrocee**® 200 mg capsule: Each capsule contains Ribavirin BP 200 mg.

**Package quantities**

**Chrocee**® 200 mg capsule: Carton of 20 capsules in blister pack.

® Registered Trade Mark

**ACI Limited**