Ribavirin® capsules

TRADE NAME:
Ribavirin® 200mg capsules
Ribavirin® 400mg capsules

GENERIC NAME:
Ribavirin

COMPOSITION
Active Ingredients: Ribavirin
* **Ribavirin®** *200mg:*
Each capsule contains as active ingredient 200mg Ribavirin
* **Ribavirin®** *400mg:*
Each capsule contains as active ingredient 400mg Ribavirin
Excipients for **Ribavirin®** *200mg & 400mg*:
Lactose monohydrate spray dried, Magnesium stearate, Croscarmellose Sodium and Avicel PH 101 (microcrystalline cellulose)

PHARMACOLIGICAL ACTION:
Three hypotheses have been proposed. One hypothesis proposed the treatment with this antiviral agent leads to decreased intracellular pools of guanosine triphosphate, thereby indirectly suppressing synthesis of viral nucleic acid. According to a second hypothesis, treatment of viral infected cells with Ribavirin results in the synthesis of RNA with abnormal 5' cap structures which, in turn, leads to inefficient translation of viral transcripts. A third hypothesis states that Ribavirin has a direct suppressive effect on viral polymerase activities.
When administered orally, Ribavirin is rapidly absorbed from GIT and there is no effect of food intake on its absorption.

INDICATIONS:
Ribavirin is indicated in:
1- Chronic hepatitis C with compensated liver disease in combination with interferon α-2a.
2- Cases where interferon is contraindicated as in liver transplantation.
3- Cases where uses of Interferon is contraindicated for reasons related to the patient.
Ribavirin is also indicated in Herpes zoster, Herpes simplex, viral respiratory infections, and viral childhood diseases like measles.

DOSAGE & ADMINISTRATION:
The recommended dosage for the treatment of chronic hepatitis C, by mouth for adult over 18 years:
Body weight < 75 kg, 400 mg in the morning & 600 mg in the evening
Body weight > 75 kg, 600 mg twice daily.
A maximal activity is achieved when Ribavirin is combined with interferon.
The duration of therapy depends on the genotype. For genotype 4 a minimum duration of therapy of 48 weeks is recommended.

CONTRAINDICATIONS:
Ribavirin is contraindicated in:
- Patients with known hypersensitivity to Ribavirin or to any component of the capsule.
- Pregnant women or lactating women.
- Men whose female partners are pregnant.
- Patients with severely impaired renal functions (creatinine clearance below 30 ml/min)
- Patients who have manifestations of chronic anemia (hemoglobin below 10 g/dl), severe cardiac disease.
- Severe hepatic dysfunction or decompensated cirrhosis (Child-Pough class C)

SIDE EFFECTS:
The most common side effect of Ribavirin is mild, reversible hemolytic anemia. Anemia associated with Ribavirin is often asymptomatic and can be managed by monitoring of the blood count and serum biochemistry.
Treatment with Ribavitin induces small elevations of serum uric acid levels.

DRUG INTERACTION:
Ribavirin doesn't inhibit CYP450 enzymes

PRECAUTIONS & WARNINGS:
-Ribavirin must not be used alone because Ribavirin monotherapy is not affective in treatment of HCV.
- The primary toxicity of Ribavirin is hemolytic anemia (hemoglobin <10 g/dl).
- Laboratory tests should be performed pretreatment and at week 2 & week 4 of therapy or more frequently if clinically indicated.
- The anemia associated with Ribavirin usually occurs within 1 to 2 weeks of initiation of therapy.
- The safety and efficacy of Ribavirin has not been established in children.
- The pharmacokinetics of Ribavirin has not been studied in patients with renal impairment and there are limited data from clinical trials on administration of Ribavirin in patients with creatinine clearance < 50 ml/min.

PACKAGE & STORAGE:
- It is supplied in strips of 6 capsules, for **Ribavirin**® 200mg and **Ribavirin**® 400 mg.
- Store below 30^{o}C, in a dry place.

Manufactured by
MINAPHARM
Pharmaceutical & Chemical Industries
10th of Ramadan - Egypt
www.minapharm.com
Tel:+2 015 413115 Fax:+2 015 413109

MINAPHARM