Viracin®

Ribavirin
Capsule

Description

Ribavirin, is a nucleoside analogue with antiviral activity and inhibits HCV polymerase in a biochemical reaction. The terminal half-life of ribavirin following administration of a single oral dose of Viracin® is about 120 to 170 hours.

Indications

Viracin® is indicated for the treatment of chronic hepatitis C (CHC) virus infection in combination with other antiviral drugs in patients with compensated liver disease not previously treated with interferon alpha and in adult CHC patients coinfected with HIV. Ribavirin should not be used alone.

Dosage and Administration

Viracin® should be taken with food. The dose of Ribavirin for Chronic Hepatitis C Monoinfection:

Adult Dose: The recommended duration of treatment for patients previously untreated with ribavirin and other antiviral drug is 12 to 24 weeks. The dose should be individualized to the patient depending on baseline disease characteristics (e.g., genotype), response to therapy and tolerability of the regimen (see the following table).

Patient Population	Treatment Regimen
Patients with genotype 1 or 4	Sofovir-C® + Peginterferon Alfa + Viracin®* for 12 weeks
Patients with genotype 2 CHC	Sofovir-C® + Viracin®* for 12 weeks
Patients with genotype 3 CHC	Sofovir-C® + Viracin®* for 24 weeks

Dosage of Viracin® is weight based (<75 kg = 1000 mg and ≥75 kg = 1200 mg). The daily dosage of Ribavirin is administered orally in two divided doses with food.

Pediatric Dose: Dosing for pediatric patients is determined by body surface area for Peginterferon Alfa and by body weight for Ribavirin. The recommended dose is 15 mg/kg/day of Ribavirin orally in two divided doses for pediatric patients ages 3-17 years.

Contraindication

•Women who are pregnant. Viracin® may cause fetal harm when administered to a pregnant woman. Viracin® is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

•Patients with hemoglobinopathies (e.g., thalassemia major or sickle-cell anemia).

•In combination with didanosine. Reports of fatal hepatic failure, as well as peripheral neuropathy, pancreatitis and symptomatic hyperlactatemia/lactic acidosis have been reported in clinical trials.

Adverse Reactions

The most common adverse reactions in adults receiving combination therapy are psychiatric and central nervous system effects, severe ocular disorder, dental and periodontal disorders & growth inhibition in children and adolescents that may be irreversible in some patients. The most common adverse reactions in pediatric subjects were similar to those seen in adults.

Warning and Precautions

Birth defects and fetal death with ribavirin: Do not use in pregnancy and for 6 months after treatment. Patients must have a negative pregnancy test prior to therapy, use at least 2 forms of contraception and undergo monthly pregnancy tests. For a male patient, it is very important for his female partner to avoid becoming pregnant during treatment and during the 7 months after treatment and do not have sex with a pregnant women.

Drug Interaction

•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.

High Risk Group

Pregnancy:

Category X. Ribavirin produced significant embryocidal and/or teratogenic effects in all animal species in which adequate studies have been conducted. Malformations of the skull, palate, eye, jaw, limbs, skeleton and gastrointestinal tract were noted. The incidence and severity of teratogenic effects increased with escalation of the drug dose. Survival of fetuses and offspring was reduced.

Nursing Mothers:

It is not known whether Ribavirin is excreted in human milk. Because many drugs are excreted in human milk and to avoid any potential for serious adverse reactions in nursing infants from ribavirin, a decision should be made either to discontinue nursing or therapy with Viracin®, based on the importance of the therapy to the mother.

Pediatric Use:

Safety and effectiveness of Ribavirin in combination with Peginterferon has not been established in pediatric patients below the age of 3 years.

Geriatric Use:

The risk of toxic reactions to this drug may be greater in patients with impaired renal function. The dose of Viracin® should be reduced in patients with creatinine clearance less than or equal to 50 ml/min; and the dose of Interferon should be reduced in patients with creatinine clearance less than 30 ml/min.

Pharmaceutical Precautions

Keep out of the reach of children. Keep in a cool & dry place. Protect from light.

Commercial Pack

Viracin® capsule: Box containing 30 capsules in 3x10's Alu-Alu form packs. Each capsule contains Ribavirin USP 200 mg.

BEXIMCO PHARMA

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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