TRIAZAVIRIN®

INTERNATIONAL NON-PROPRIETARY NAME (INN): Riamilovir

DOSAGE FORM AND STRUCTURE:
Active Ingredient: sodium methylthionitrooxodihydrotriazolotriazinide dihydrate (triazavirin®) - 250 mg;
Excipients: calcium stearate - 2 mg;
The weight of the capsule contents is 252 mg.
The composition of the capsule shell:
Capsule body: titanium dioxide (E171), yellow quinoline (E104), yellow "sunset" (E110), medical gelatine;
Capsule cap: titanium dioxide (E171), azorubine (E122), medical gelatin.
The weight of the capsule with its contents is 328 mg.

DESCRIPTION:
Hard gelatine capsules No. 1 with a yellow body and a red cap. The capsule contains a fine-grained powder or granules of yellow or yellow-green color.

PHARMACOLOGICAL CLASSIFICATION: Antiviral agent.

ATC CODE: J05AX Other antivirals.

PHARMACODYNAMICS:
The active substance of Triazavirin® is a synthetic analog of the bases of purine nucleosides (guanine) with a pronounced antiviral effect. It has a wide range of antiviral activity against RNA-containing viruses.
The main mechanism of action of Triazavirin® is the inhibition of viral RNA synthesis and replication of genomic fragments.

PHARMACOKINETICS
After an oral administration, the drug is rapidly absorbed in the gastrointestinal tract. The maximum concentration (Cmax) is reached on average after 1-1.5 hours. Cmax in recommended dosing regimen is on average 4.8 μg / ml. AUC (area under the pharmacokinetic curve "concentration - time") of blood is 12.8 μg / h * ml. The elimination half-life (T1 / 2) is 1-1.5 hours. From 15 to 45% of sodium methylthionitrooxodihydrotriazolotriazinide is excreted unchanged by the kidneys. The average estimated clearance value is 246 ml / min.

INTENDED USES:
As part of the complex therapy of influenza in adult patients.

CONTRAINDICATIONS:
- Hypersensitivity to the drug components;
- Pregnancy;
- Lactation;
- Children under 18 years old (efficacy and safety are not determined);
- Renal / liver failure (efficacy and safety are not determined).

DOSAGE AND ADMINISTRATION:

Triazavirin® is administered orally, irrespective of meals, with a sufficient amount of water. The capsule should be swallowed whole, it is not recommended to chew or crush the capsule.
The drug administration should be started no later than on the 2nd day from the onset of the disease (the onset of clinical symptoms of influenza).
The recommended dose is 1 capsule (250 mg) 3 times a day for 5 days. If necessary, and upon the doctor's recommendations, the treatment can be continued up to 7 days.
The maximum daily dose is 3 capsules (750 mg).

SIDE EFFECTS:
Allergic response.
From the digestive system - dyspeptic disorders (meteorism, diarrhea, nausea, vomiting).

OVERDOSE:
Symptoms: nausea, vomiting, dyspeptic disorders, stomach pain. Treatment: symptomatic therapy. If these symptoms are manifested, stop taking the drug and consult a doctor.

INTERACTION WITH OTHER DRUGS:
Interaction with analogues of purine and pyrimidine bases during antitumor therapy can increase the toxicity of the drug. In case of simultaneous use of ribavirin, the dose of the latter should be reduced.

PREGNANCY AND LACTATION:
Because of the lack of strictly controlled studies in humans, the use of the drug during pregnancy is contraindicated (see the section on "Contraindications").
The use of the drug during breastfeeding has not been studied; therefore if it is necessary to use the drug during lactation, breastfeeding should be discontinued.

INFLUENCE ON THE ABILITY TO DRIVE VEHICLES AND OPERATE MECHANISMS:
Influence on the ability to drive vehicles and operate mechanisms has not been studied; however, based on the spectrum of adverse reactions on the drug, no effect on these activities is expected.

STORAGE CONDITIONS:
Store in a dry place, at a temperature not exceeding 25°C (77°F). Keep out of the reach of children.

SHELF LIFE:
5 years. Do not use the drug after the expiration date indicated on the package.

MANUFACTURER: LLC "Plant Medsintez". http://www.medsintez.com/en