Hepaximin

Rifaximin Tablet

Composition:
Hepaximin 200 Tablet: Each film coated tablet contains Rifaximin BP 200 mg.
Hepaximin 550 Tablet: Each film coated tablet contains Rifaximin BP 550 mg.

Pharmacology:
Rifaximin is a non-aminoglycoside, semi-synthetic, antibacterial derived from Rifamycin. Rifaximin acts by binding to the beta-subunit of bacterial DNA-dependent RNA polymerase resulting in inhibition of bacterial RNA synthesis.

Indications:
Acute infectious diarrhoea including travelers' diarrhoea, Diarrhoea predominant Irritable Bowel Syndrome (IBS-D) and Hepatic Encephalopathy.

Dosage and Administration:

Indications	Dose	Frequency
Acute Infectious Diarrhoea including Travelers' Diarrhoea	200 mg	Three times daily for 3 days
Diarrhoea predominant Irritable Bowel Syndrome (IBS-D)	550 mg	Three times daily for 14 days
Hepatic Encephalopathy	550 mg	Twice daily

Contraindications:
Hepaximin is contraindicated in patients with a hypersensitivity to Rifaximin, or any of the Rifamycin antimicrobial agents, or any of the components of this preparation.

Side effects:
Common side effects are nausea, vomiting, abdominal pain, flatulence, headache and dizziness.

Use in Special Group:
Use in Pregnancy: Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Hepaximin should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus.

Use in Lactation: It is not known whether Rifaximin is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for adverse reactions in nursing infants from Hepaximin, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Use in Children:
The safety and effectiveness of Hepaximin 200 mg in pediatric patients with travelers' diarrhoea less than 12 years of age have not established.
The safety and effectiveness of Hepaximin 550 mg for hepatic encephalopathy have not been established in patients <18 years of age.

Geriatric use:
Clinical studies of Hepaximin tablets did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently than younger subjects.

Use in Renal Insufficient Patients:
The pharmacokinetics of Rifaximin in patients with impaired renal function has not been studied.

Use in Hepatic Insufficient Patients:
No dosage adjustment with Rifaximin is necessary due to its limited systemic absorption. Nonetheless, caution should be exercised when Rifaximin is administered to patients with severe hepatic impairment.

Drug Interaction:
Although In vitro studies demonstrated the potential of Rifaximin to interact with cytochrome P450 (CYP3A4), a clinical drug-drug interaction study demonstrated that Rifaximin did not significantly affect the pharmacokinetics of midazolam. An additional clinical drug-drug interaction study showed no effect of Rifaximin on the presystemic metabolism of an oral contraceptive containing ethinyl estradiol and norgestimate. Therefore, clinical interactions with drugs metabolized by human cytochrome P450 isozymes are not expected.

Storage:
- Store below 30^0C, keep in dry place & protect from light.
- Keep out of the reach of children.

Packing:
Hepaximin 200 Tablet: Each box contains 20 tablets in alu-alu blister pack.
Hepaximin 550 Tablet: Each box contains 10 tablets in alu-alu blister pack.

Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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