Ibida®

Rifaximin BP

Composition

Ibida® Tablet 200 mg: Each film coated tablet contains Rifaximin BP 200 mg.
Ibida® Tablet 550 mg: Each film coated tablet contains Rifaximin BP 550 mg.

Pharmacolgy

Rifaximin is a non-aminoglycoside, semi-synthetic, non-systemic antibiotic derived from rifamycin. Rifaximin acts by binding to the beta-subunit of bacterial DNA-dependent RNA polymerase resulting in inhibition of bacterial RNA synthesis.
Rifaximin is a semisynthetic, rifamycin-based non-systemic antibiotic. Very little of the drug will pass the gastrointestinal wall into the circulation as is common for other types of orally administered antibiotics. Rifaximin inhibits bacterial RNA synthesis by its action on the beta-subunit of the DNA-dependent RNA polymerase. It shows the same broad-spectrum activity as rifamycin which exerts bactericidal action against many species of Gram-positive and Gram-negative, aerobic and anaerobic bacteria.

Indication

Acute Infectious Diarrhea including Travelers' Diarrhea
Diarrhea predominant Irritable Bowel Syndrome (IBS-D)
Hepatic Encephalopathy (HE).

Dose & Administration

Rifaximin tablets can be administered orally with or without food.

Indication	Dose	Frequency
Acute Infectious Diarrhea including Travelers' Diarrhea	200 mg	Three times Daily for 3 Days
Diarrhea predominant Irritable Bowel Syndrome (IBS-D)	550 mg	Three times Daily for 14 Days
Hepatic Encephalopathy (HE)	550 mg	Twice daily

Contra-indication

Rifaximin tablets are contraindicated in patients with a hypersensitivity to Rifaximin, any of the rifamycin antimicrobial agents, or any of the components in Rifaximin tablets.

Warning and Precaution

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

Hepatic Insufficiency:
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.

Side Effects

All medicines may cause side effects but many people have no or minor side effects. Common side effects of Rifaximin include dizziness, gas, headache, nausea, tiredness.

Use in Pregnancy & Lactation

Use in Pregnancy:
Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Rifaximin 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 Rifaximin, 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 & Adolescents

Use in Children:
The safety and effectiveness of Rifaximin 200 mg in pediatric patients with travelers' diarrhoea less than 12 years of age have not been established. The safety and effectiveness of Rifaximin 550 mg for hepatic encephalopathy & diarrhea predominant irritable bowel syndrome have not been established in patients less than 18 years of age.

Use in Adolescents:
Clinical studies of Rifaximin tablets did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently than younger subjects.

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.

Overdose

No specific information is available on the treatment of overdosage with Rifaximin. In clinical studies at doses higher than the recommended dose, adverse reactions were similar in subjects who received doses higher than the recommended dose and placebo. In the case of overdosage, discontinue Rifaximin, treat symptomatically, and institute supportive measures as required.

Storage

Store at temperature not exceeding 30ºC in a dry place.
Protect from light.

Packing

Ibida® Tablet 200 mg: Each box contains 2x10's tablets in Alu-Alu blister Pack.
Ibida® Tablet 550 mg: Each box contains 2x10's tablets in Alu-Alu blister Pack.

Medicine: Keep out of reach of children

Healthcare

Manufactured by
Healthcare Pharmaceuticals Ltd.
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