Henlix®

Rifaximin

Description

Henlix® is a preparation of Rifaximin which is a semi-synthetic, Rifamycin based non-systemic antibiotic. Rifaximin acts by binding to the beta-subunit of bacterial DNA-dependent RNA polymerase resulting in inhibition of bacterial RNA synthesis. It results in inhibition of bacterial protein synthesis and consequently inhibits the growth of bacteria. 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.

Indications

Henlix® tablet is indicated for -

- Travelers' Diarrhea (TD) caused by noninvasive strains of *Escherichia coli*
- Irritable Bowel Syndrome with Diarrhea (IBS-D)
- Reduction in rsk of overt Hepatic Encephalopathy (HE)

Dosage & administration

The recommended dose of Henlix® tablet -

Travelers' Diarrhea in adult and children over 12 years: One Henlix® 200 tablet three times daily for 3 days.

Irritable Bowel Syndrome in adults over 18 years: One Henlix® 550 tablet three times daily for 14 days.

Hepatic Encephalopathy in adults over 18 years: One Henlix® 550 tablet twice daily.

Use in pregnancy and lactation

Rifaximin is pregnancy category C. Rifaximin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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.

Side effects

The most common side effects of Rifaximin are peripheral edema, nausea, flatulence, vomiting, dizziness, fatigue, ascites, muscle spasms, pruritus, abdominal pain, depression and nasopharyngitis.

Contraindications

Rifaximin is contraindicated in patients with a known history of hypersensitivity to Rifaximin, Rifamycin antimicrobial agents, or any of the components of the formulation.

Precautions

Rifaximin is not found to be effective in patients with diarrhea complicated by fever or blood in the stools due to pathogens other than *Escherichia coli*. Rifaximin therapy should be discontinued if diarrhea symptoms get worse or persist for more than 24-48 hours and an alternative antibiotic therapy should be considered. Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Drug interactions

Rifaximin 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 pre-systemic 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 the case of overdosage, discontinue Rifaximin, treat symptomatically, and institute supportive measures are required.

Pharmaceutical precautions

Store in a cool and dry place protected from light. Keep out of the reach of children.

Presentation

Henlix® 200 tablet: Each coated tablet contains Rifaximin BP 200 mg.
Henlix® 550 tablet: Each coated tablet contains Rifaximin BP 550 mg.

Package quantities

Henlix® 200 tablet: Carton of 18 tablets in blister pack.
Henlix® 550 tablet: Carton of 10 tablets in blister pack.

ACI Limited
Narayanganj, Bangladesh