RIFAXIM[®] Rifaximin



Composition:

RIFAXIM 200 Tablet: Each film coated tablet contains Rifaximin BP 200 mg.

RIFAXIM 550 Tablet: Each film coated tablet contains Rifaximin BP 550 mg.

Pharmacology:

Rifaximin is a semi-synthetic, 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.

Indications:

- Treatment of traveler's diarrhoea by noninvasive strains of E. coli.
- Reduction in risk of hepatic encephalopathy.
- Bacterial over growth of irritable bowel syndrome.

Dosage & Administration:

Traveler's Diarrhoea: For patients >12 years of age - 200 mg 3 times daily for 3 days.

Hepatic Encephalopathy: For patients >18 years of age - 550 mg 2 times daily.

Bacterial over growth of irritable bowel syndrome: 400 mg 3 times daily for 10 days or 550 mg 3 times daily for 14 days.

Rifaximin can be taken with or without food.

Precautions:

Rifaximin is not found to be effective in patients with diarrhoea complicated by fever and/or blood in the stools. Rifaximin therapy should be discontinued if diarrhoea symptoms get worse or persist for more than 24-48 hours and an alternative antibiotic therapy should be considered. Pseudo-membranous 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 diarrhoea subsequent to the administration of antibacterial agents.

Side effects:

Side effects include flatulence, headache, abdominal pain, rectal tenesmus, defecation urgency, nausea, constipation, pyrexia, vomiting.

Contraindications:

Rifaxim is contraindicated in patients with a hypersensitivity to Rifaximin or to any of the rifamycin antimicrobial agents, or any components of this product.

Drug Interaction:

In an in-vitro study has suggested that Rifaximin induces CYP3A4. However, in patients with normal liver function, Rifaximin at the recommended dosing regimen is not expected to induce CYP3A4.

Use in Pregnancy & Lactation:

Pregnancy category C; It is not known whether Rifaximin is excreted in mother's milk or not.

Overdose:

No specific information is available on the treatment of over dosage with Rifaximin. In case of over dosage, discontinue Rifaximin, treat symptomatically and institute supportive measures as required.

Storage:

Store in cool and dry place, protect from light and keep away from children reach.

How supplied:

RIFAXIM 200 Tablets: 10 Tablets X 10 Blisters. RIFAXIM 550 Tablets: 10 Tablets X 10 Blisters.

Manufactured by:



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