

W=110mm,H=175mm



## Rifamax<sup>®</sup>

Rifaximin

### Presentation

Rifamax<sup>®</sup> 200 tablet: Each tablet contains Rifaximin BP 200 mg.

Rifamax<sup>®</sup> 550 tablet: Each tablet contains Rifaximin BP 550 mg.

### Description

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.

### Indications & Uses

Treatment of traveler's diarrhea by noninvasive strains of *E. coli*, reduction in risk of overt hepatic encephalopathy & bacterial over growth of irritable bowel syndrome.

### Dosage & Administration

Traveler's Diarrhea: For patients  $\geq 12$  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.

Can be taken with or without food.

### Side effects

Side effects include flatulence, headache, abdominal pain, rectal tenesmus, defecation urgency, nausea, constipation, pyrexia, vomiting. Reactions have been reported, including anaphylaxis, angioneurotic edema, and exfoliative dermatitis.

### Precautions

Rifaximin is not found to be effective in patients with diarrhea complicated by fever and/or blood in the stools. 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.

### Pregnancy & Lactation

Pregnancy category C. It is not known whether Rifaximin is excreted in human milk or not.

### Contraindications

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

### Special population

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

**Hepatic Impairment:** The systemic exposure of Rifaximin was markedly elevated in patients with hepatic impairment compared to healthy subjects.

### Drug interactions

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.

### Over dosage

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

Do not store above 30°C temperature.

### Commercial pack

Rifamax<sup>®</sup> 200 tablet: Each box contains 1 blister strip of 10 tablets.

Rifamax<sup>®</sup> 550 tablet: Each box contains 1 blister strip of 10 tablets.

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V.N. 03  
RFX