Faxan

Rifaximin BP 200mg & 550mg Tablet

Composition: Faxan-200: Each Film Coated Tablet Contains Rifaximin BP 200mg.

Faxan-550 : Each Film Coated Tablet Contains Rifaximin BP 550mg.

Pharmacology: Rifaximin is an antibacterial drug. In healthy subjects, the mean time to reach peak rifaximin plasma concentrations was about an hour and the mean Cmax ranged 2.4 to 4 ng/mL after a single dose and multiple doses. Rifaximin is moderately bound to human plasma proteins. In vivo, the mean protein binding ratio was 67.5% in healthy subjects and 62% in patients with hepatic impairment when Rifaximin was administered. The mean half-life of rifaximin in healthy subjects at steady-state was 5.6 hours and was 6 hours in IBSD (Irritable bowel syndrome with diarrhea) patients. In an in vitro study rifaximin was metabolized mainly by CYP3A4.

Indications: Faxan 200 tablets are used to treat traveler's diarrhea by noninvasive strains of *E. coli* in adults and children at least 12 years of age. Faxan 550 tablets are used to prevent episodes of hepatic encephalopathy in people at least 18 years of age who have liver disease. Rifaximin tablet is used to treat bacterial over growth of irritable bowel syndrome.

Dosage and administration: Traveler's Diarrhea: The recommended dose of Rifaximin is one 200mg tablet taken orally three times a day for 3 days. Hepatic Encephalopathy: The recommended dose of Rifaximin is one 550mg tablet taken orally two times a day for 1 to 3 weeks. Rifaximin can be administered orally, with or without food. Bacterial over growth of irritable bowl syndrome Rifaximin 400mg, 3 times daily for 10 days. Or, as directed by the registered physician.

Contraindication: Rifaximin is contraindicated in patients with known hypersensitivity to the active substance or to any other excipients of this medicine.

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 administered of antibacterial agents.

Side effects: The adverse effects have been reported with the use of Rifaximin are-flatulence, headache, abdominal pain, nausea, vomiting, constipation, pyrexia.

Use in Pregnancy and lactation: Pregnancy category C. No adequate and well-controlled studies in pregnant women. However, this drug should be used during pregnancy only if clearly needed. It is not known whether Rifaximin is excreted in human milk.

Use in Child: There is no data available.

Drug Interactions: 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.

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 below 30°C in a dry place.

Packing: Faxan-200: Each box contains 14's tablets in blister pack.

Faxan-550: Each box contains 14's tablets in blister pack.

DRUG INTERNATIONAL LTD.