Rifaxin

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Composition:
Rifaxin 200 Tablet: Each film coated tablet contains Rifaximin BP 200 mg.
Rifaxin 550 Tablet: Each film coated tablet contains Rifaximin BP 550 mg.

Pharmacology:
Rifaximin is a non-aminoglycoside semi-synthetic, nonsystemic antibiotic derived from rifamycin. Rifaximin acts by binding to the beta-subunit of bacterial deoxyribonucleic acid (DNA)-dependent ribonucleic acid (RNA) polymerase enzyme resulting in inhibition of bacterial RNA synthesis.

Dosage and Administration:
Rifaxin 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 for 1 to 3 weeks

Contraindications:
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.

Precaution:
Rifaximin is not found to be eyective 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 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.

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.

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.

Use in Pregnancy & Lactation:
Pregnancy: Pregnancy category 'C'. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.
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 tablets, 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.
Pediatric Use: The safety and effectiveness of Rifaximin 200 mg in pediatric patients less than 12 years of age have not been established. The safety and effectiveness of Rifaximin 550 mg have not been established in patients less than 18 years of age.
Geriatric Use: Clinical studies of Rifaximin 200 mg tablets did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently than younger subjects. In the controlled trial with Rifaximin 550 mg, 19.4% were 65 and over, while 2.3% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, but greater sensitivity of some older individuals cannot be ruled out.
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.

Drug Interactions:
Although in vitro studies demonstrated the potential of Rifaximin to interact with cytochrome P450 3A4 (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 isoenzymes are not expected.

Storage:
Do not store above 30^{0}C. Protect from light. Keep out of the reach of children.

Packaging:
Rifaxin 200 Tablet: Each box contains 3x8's tablets in blister pack.
Rifaxin 550 Tablet: Each box contains 2x8's tablets in blister pack.

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Manufactured by
ZISKA PHARMA **Ziska Pharmaceuticals Ltd.**
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