

Rifaximin BP

COMPOSITION

Aximin™200 Tablet: Each film-coated tablet contains Rifaximin BP 200 mg.
Aximin™550 Tablet: Each film-coated tablet contains Rifaximin BP 550 mg.

DESCRIPTION

Aximin™(Rifaximin) is a non-aminoglycoside, semi-synthetic, non-systemic broad spectrum antibiotic derived from Rifamycin SV. Rifaximin is a structural analog of Rifampin has minimal systemic absorption. Rifaximin acts by binding to the beta-subunit of bacterial DNA-dependent RNA polymerase resulting in inhibition of bacterial RNA synthesis.

INDICATIONS

■ Travelers' diarrhea ■ Hepatic encephalopathy ■ Irritable bowel syndrome ■ Infectious diarrhea

PHARMACOKINETICS

Absorption: **Aximin™**(Rifaximin) is poorly absorbed from the gastrointestinal tract. Systemic absorption of Rifaximin is low during fasting state and when administered within 30 minutes of a high fat meal.

Distribution: **Aximin™**(Rifaximin) is moderately bound to human plasma proteins. In vivo, the mean protein binding ratio was 67.5% in healthy volunteers and 62% in patients with hepatic impairment. 80% to 90% of orally administered Rifaximin is concentrated in the gut with less than 0.2% in the liver and kidney, and less than 0.1% in other tissues.

Metabolism: The enzymes responsible for **Aximin™**(Rifaximin) metabolism are unknown. Only absorbed Rifaximin undergoes metabolism with minimal renal excretion of the unchanged drug.

Excretion: 97% of the **Aximin™**(Rifaximin) dose almost exclusively and completely excreted in feces as unchanged drug, mean 0.32% of the dose excreted in urine.

Therapeutic Drug Concentration: In-case of Gram-positive bacteria, MIC ranging from 0.015 to 2 mcg/ml. Antibacterial activity of Rifaximin is greater against gram-positive than against gram-negative bacteria.

Time to peak Concentration: 1.2 to 1.9 hours.

DOSAGE & ADMINISTRATION

Aximin™(Rifaximin) tablets can be administered orally with or without food. The recommended dosage guideline is given below:

Travelers' diarrhea/ Infectious diarrhea : 200 mg three times a day for 3 days
Hepatic encephalopathy : 550 mg twice daily
Irritable bowel syndrome : 550 mg three times a day for 14 days

CONTRAINDICATIONS

Aximin™(Rifaximin) is contraindicated in patients with hypersensitivity to any components of Rifaximin or Rifamycin.

SIDE EFFECTS

Most common side effects are headache, abdominal pain, flatulence, defecation urgency, nausea, peripheral edema, dizziness and fatigue.

USE IN PREGNANCY

Based on animal data, **Aximin™**(Rifaximin) may cause fetal harm. There are no adequate and well controlled studies in pregnant women. Pregnancy category is C. Rifaximin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

USE IN LACTATION

It is not known whether **Aximin™**(Rifaximin) is excreted in human milk or not.

USE IN CHILDREN

The safety and effectiveness of **Aximin™**(Rifaximin) 200 mg in pediatric patients with travelers' diarrhea less than 12 years of age have not been established. The safety and effectiveness of Rifaximin 550 mg for Hepatic encephalopathy have not been established in patients < 18 years of age.

WARNINGS & PRECAUTIONS

■ **Travelers' diarrhea not caused by E.coli:** **Aximin™**(Rifaximin) is not effective in diarrhea complicated by fever and/or blood in the stool or diarrhea due to pathogens other than *E.coli*. If diarrhea symptoms get worse or persist for more than 24-48 hours Rifaximin should be discontinued and alternative antibiotics should be considered.

■ **Clostridium difficile-Associated Diarrhea:** If diarrhea occurs after therapy or does not improve or worsens during therapy alternative antibiotics may be chosen.

■ **Hepatic Impairment:** Caution should be exercised in patients with severe hepatic impairment.

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

DRUG INTERACTIONS

Clinical study demonstrated that, Rifaximin did not inhibit cytochrome P450 isoenzymes at concentrations ranging from 2 to 200 ng/mL. Therefore, Rifaximin has no clinical interactions with those drugs which are metabolized by human cytochrome P450 isoenzymes. Two clinical drug-drug interaction studies using midazolam and an oral contraceptive containing ethinyl estradiol and norgestimate demonstrated that Rifaximin did not alter the pharmacokinetics of these drugs.

OVER DOSAGE

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

SUPPLY

Aximin™200 Tablet: Each carton contains 1x10 tablets in Alu-Alu blister strip.
Aximin™550 Tablet: Each carton contains 1x10 tablets in Alu-Alu blister strip.

Keep all medicines out of reach of children.
Store in a cool and dry place, away from light.

* Further information is available on request.



Manufactured by:
The ACME Laboratories Ltd.
Dhamrai, Dhaka, Bangladesh

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