71 mm

220 mm

Nixaf® Tablets
(Rifaximin)

Description:

Nixaf® tablets contain rifaximin, a non-aminoglycoside semi-synthetic, nonsystemic antibiotic derived from rifamycin SV. Rifaximin is a structural analog of rifampin

Composition:
Each film coated tablet contains:
Rifaximin Ph. Eur.....200mg

Each film coated tablet contains:
Rifaximin Ph. Eur.....550mg

Clinical Pharmacology:
Mode of Action
Rifaximin is a non-aminoglycoside semi-synthetic antibacterial derived from rifamycin SV. Rifaximin acts by binding to the beta-subunit of bacterial DNA-dependent RNA polymerase resulting in inhibition of bacterial RNA synthesis

Pharmacokinetic Properties:
Absorption
Rifaximin has low intestinal permeability and low aqueous solubility and therefore, it is poorly absorbed from the gastrointestinal tract, having a bioavailability of about only 0.4%

Distribution
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 rifixamin 550mg was administered

Metabolism and Excretion
In a mass balance study, after administration of 400mg 14C-rifaximin orally to healthy volunteers, of the 96.94% total recovery, 96.62% of the administered radioactivity was recovered in feces almost exclusively as the unchanged drug and 0.32% was recovered in urine mostly as metabolites with 0.03% as the unchanged drug. Rifaximin accounted for 18% of radioactivity in plasma. This suggests that the absorbed rifaximin undergoes metabolism with minimal renal excretion of the unchanged drug. The enzymes responsible for metabolizing rifaximin are unknown. In a separate study, rifaximin was detected in the bile after cholecystectomy in patients with intact gastrointestinal mucosa, suggesting biliary excretion of rifaximin

Therapeutic Indications:
Hepatic Encephalopathy
Rifaximin 550mg is indicated for reduction in risk of overt hepatic encephalopathy (HE) recurrence in patients ≥ 18 years of age and also indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults

Travelers' Diarrhea
Rifaximin 200mg is indicated for the treatment of patients (≥ 12 years of age) with travelers' diarrhea caused by noninvasive strains of Escherichia coli

Dosage and administration:
Hepatic Encephalopathy
The recommended dose of rifaximin is one 550mg tablet taken orally two times a day, with or without food
Irritable Bowel Syndrome with Diarrhea (IBS-D)
The recommended dose of rifaximin is one 550mg tablet taken orally three times a day for 14 days
Travelers' Diarrhea
The recommended dose of rifaximin is one 200mg tablet taken orally three times a day for 3 days.
Rifaximin can be administered orally, with or without food

OR
As directed by the physician

Contraindications:
Rifixamin is contraindicated in patients with a hypersensitivity to rifaximin, any of the rifamycin antimicrobial agents, or any of the components in rifaximin. Hypersensitivity reactions have included exfoliative dermatitis, angioneurotic edema, and anaphylaxis

Warnings:
Severe (Child-Pugh C) Hepatic Impairment
There is increased systemic exposure in patients with severe hepatic impairment. Animal toxicity studies did not achieve systemic exposures that were seen in patients with severe hepatic impairment

Special Precautions:
Pregnancy
Pregnancy Category C
Nursing mothers
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, 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
Paediatric Use
The safety and effectiveness of rifaximin 550mg for hepatic encephalopathy have not been established in patients < 18 years of age
Geriatric Use
In the controlled trial with rifaximin 550mg for hepatic encephalopathy, 19.4% were 65 years and over, while 2.3% were 75 years and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out

Adverse Reactions:
Common
Peripheral oedema, nausea, elevated liver enzyme (ALT), dizziness, fatigue, ascites, muscle spasm, pruritis, abdominal pain, abdominal distension, anemia, cough, depression, insomnia, nasopharyngitis, upper abdominal pain, arthralgia, back pain, constipation, dyspnea, pyrexia and rash

Uncommon
Vertigo, lower abdominal pain, abdominal tenderness, dry mouth, esophageal variceal bleed, stomach discomfort, chest pain, generalized oedema, influenza like illness, pain, cellulitis, pneumonia, rhinitis, upper respiratory tract infection, confusion, fall, procedural pain, weight increase, anorexia, dehydration, hyperglycemia, hyperkalemia, hypoglycemia, hyponatremia, myalgia, pain in extremities, amnesia, disturbance in attention, hypoesthesia, memory impairment, tremor, confusional state, epistaxis and hypotension

Overdosage:
At doses higher than the recommended dose (> 1100mg/day for hepatic encephalopathy), adverse reactions were similar in subjects who received the recommended doses. In the case of overdose, discontinue rifaximin, treat symptomatically and institute supportive measures as required

Stability:
See expiry on the pack

Presentation:
Nixaf® 200mg tablets in a pack of 10's
Nixaf® 550mg tablets in a pack of 10's

Instructions:
Keep out of reach of children
Avoid exposure to heat, light and humidity
Store between 15 to 30°C
Improper storage may deteriorate the medicine

نگزیف® ٹیبلٹ
(ریفگزیمن)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں
بچوں کی پہنچ سے دور رکھیں
دوا کو دھوپ، گرمی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ
کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی

Manufactured by:
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