Orifax®

(Rifaximin)

550mg Tablets

اوری فیکس ۵۵۰ ملی گرام

(ریفیکسامین)

COMPOSITION:
Orifax 550mg Tablet
Each film coated tablet contains:
Rifaximin (BP Specs) ..... 550 mg.
Product complies BP Specifications.

CLINICAL PARTICULARS
Therapeutic indications:
Treatment of traveller's diarrhea (TD) caused by non-invasive strains of *Escherichia coli* in adult and pediatric patients of 12 years of age and older, Reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults and Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

Posology and method of administration:
RIFAXIMIN can be taken with or without food.

Condition	Recommended Dosage Regimen
HE	One 550 mg tablet 2 times a day
IBS-D	One 550 mg tablet 3 times a day for 14 days. Patients who experience recurrence can be retreated up to two times with the same regimen.

CONTRAINDICATIONS:
History of hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any of the components of ORIFAX.

Special warnings and precautions for use
Travelers' Diarrhea Not Caused by E. coli:
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 to 48 hours, discontinue RIFAXIMIN and consider alternative antibiotics.

Clostridium difficile-Associated Diarrhea:
Evaluate if diarrhea occurs after therapy or does not improve or worsens during therapy.

Hepatic Impairment:
Use with caution in patients with severe Child-Pugh Class C.

Interaction with other medicinal products and other forms of interaction
Warfarin: Monitor INR and prothrombin time; dose adjustment of warfarin may be needed to maintain target INR range.

FERTILITY, PREGNANCY AND LACTATION
Pregnancy:
May cause harm to fetus.

Breast feeding:
There is no information regarding the presence of rifaximin in human milk, the effects of rifaximin on the breastfed infant, or the effects of rifaximin on milk production.

Effects on ability to drive and use machines
Rifaximin can also cause dizziness do not drive or operate.

Undesirable effects:
• Travelers' Diarrhea (.TD) in 2%: Headache
• Hepatic Encephalopathy (HE) in 10%: Peripheral edema, nausea, dizziness, fatigue, and ascites.
• Irritable Bowel Syndrome with Diarrhea (IBS-D) in 2%: ALT increased and nausea.

Overdose
Symptoms and management
No specific information is available on the treatment of overdosage with RIFAXIMIN. In the case of overdosage, discontinue RIFAXIMIN, treat symptomatically, and institute supportive measures as required.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Pharmacotherapeutic classification: Anti-Bacterial.
Rifaximin acts by inhibiting RNA synthesis in susceptible bacteria by binding to the beta subunit of bacterial deoxyribonucleic acid (DNA)-dependent ribonucleic acid (RNA) polymerase enzyme. This binding blocks translocation, which stops transcription.

Pharmacokinetic properties
Absorption
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 of RIFAXIMIN 550 mg.

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 RIFAXIMIN was administered.

Metabolism:
Rifaximin was metabolized mainly by CYP3A4.

Elimination:
The mean half-life of rifaximin in healthy subjects at steady-state was 5.6 hours and was 6 hours in IBS-D patients.

Special precautions for storage
Do not refrigerate.

STORAGE CONDITIONS AND OTHER INFORMATION:
• Dosage as directed by physician.
• To be dispensed on the prescription of a registered medical practetioner only.
• Store below 30°C in a dry place, protect from light.
• Keep out of the reach of children.

PRESENTATION:
Orifax 550mg tablet is available in blister pack of 10's.

ہدایات:
- **خوراک** ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
- دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچوں کی پہنچ سے دور رکھیں۔

Mfg. Lic. No.: 000755
Manufactured by:
Kaizen Pharmaceuticals (Pvt.) Ltd.
E-127-129, North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

Art no: 618/1