

Rifaximin FDA approved indications:

Treatment of moderate to severe IBS without constipation 7

Chronic prevention of Hepatic Encephalopathy

Treatment of moderate to severe travelers' diarrhea

- Efficacious and well-tolerated
- Gut-directed antibiotic
- Virtually absence of GI absorption
- Low bacterial-resistance profile
- Shows 'Eubiotic' effects



Rifaximin F.C. tablets 200, 550 mg



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XIGUT- rifaximin film coated tablet Actoverco Pharmaceuticals.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use XIGUT safely and effectively.

XIGUT (rifaximin) F.C. tablets, for oral use

Initial U.S. Approval: 2004

• To reduce the development of drug-resistant bacteria and maintain the effectiveness of XIGUT and other antibacterial drugs, XIGUT should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

INDICATIONS AND USAGE

XIGUT is a rifamycin antibacterial indicated for:

- Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults
- Reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults.
- Treatment of travelers' diarrhea (TD) caused by noninvasive strains of Escherichia coli in adult and pediatric patients 12 years of age and older.

Limitations of Use

• TD: Do not use in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli.

DOSAGE AND ADMINISTRATION

Condition	Recommended Dosage Regimen
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
HE	One 550 mg tablet 2 times a day
TD	One 200 mg tablet 3 times a day for 3 days

• XIGUT can be taken with or without food.

DOSAGE FORMS AND STRENGTHS

200 mg and 550 mg F.C. tablets.

CONTRAINDICATIONS

History of hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any of the components of XIGUT.

WARNINGS AND PRECAUTIONS

- Travelers' Diarrhea Not Caused by E. coli: XIGUT was 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 XIGUT 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) hepatic impairment.
- Concomitant P-glycoprotein (P-gp) inhibitors (e.g., cyclosporine): Caution should be exercised when concomitant use of XIGUT and a P-glycoprotein inhibitor is needed

ADVERSE REACTIONS

Most common adverse reactions:

IBS-D (≥2%)	ALT increased, nausea
HE (≥10%)	Peripheral edema, nausea, dizziness, fatigue, and ascites
TD (≥2%)	Headache

To report SUSPECTED ADVERSE REACTIONS, contact Actoverco Pharmaceuticals.

DRUG INTERACTIONS

Warfarin: Monitor INR and prothrombin time; dose adjustment of warfarin may be needed to maintain target INR range.

USE IN SPECIFIC POPULATIONS

Pregnancy: May cause fetal harm (08.2020)

