Xifaxan

(Rifaximin) - Salix

THERAPEUTIC CLASS
Semisynthetic rifampin analog

DEA CLASS
RX

INDICATIONS
(200mg) Treatment of travelers' diarrhea caused by noninvasive strains of *Escherichia coli* in patients ≥12 yrs of age. (550mg) Reduction in risk of overt hepatic encephalopathy (HE) recurrence in patients ≥18 yrs of age.

ADULT DOSAGE
Adults: Travelers' Diarrhea: 200mg tid for 3 days. HE: 550mg bid.

PEDIATRIC DOSAGE
Pediatrics: Travelers' Diarrhea: ≥12 Yrs: 200mg tid for 3 days.

HOW SUPPLIED
Tab: 200mg, 550mg

WARNINGS/PRECAUTIONS
Should not be used in patients with diarrhea complicated by fever and/or blood in the stool or diarrhea due to pathogens other than *E. coli*. D/C if diarrhea symptoms worsen or persist >24-48 hrs; consider alternative antibiotic therapy. *Clostridium difficile*-associated diarrhea (CDAD) reported; d/c if CDAD suspected or confirmed. May result in bacterial resistance with prolonged use in the absence of proven or strongly suspected bacterial infection or a prophylactic indication. Caution with severe hepatic impairment (Child-Pugh Class C); may increase systemic exposure.

ADVERSE REACTIONS
Flatulence, headache, abdominal pain, rectal tenesmus, nausea, peripheral edema, dizziness, fatigue, ascites, muscle spasms, pruritus, abdominal distention, anemia, cough, depression.

DRUG INTERACTIONS
Caution with P-glycoprotein inhibitors (eg, cyclosporine); may increase systemic exposure.

PREGNANCY
Category C, not for use in nursing.

MECHANISM OF ACTION
Semisynthetic rifampin analog; binds to β-subunit of bacterial DNA-dependent RNA polymerase, resulting in inhibition of bacterial RNA synthesis.

PHARMACOKINETICS
Absorption: Administration with consecutive dosing, fasting/fed conditions, and Child-Pugh Class (A, B, C) resulted in different pharmacokinetic parameters; refer to PI. **Distribution:** (550mg dose) Plasma protein binding (67.5%, healthy), (62%, hepatic impairment). **Elimination:** (400mg, healthy) Feces (96.62% unchanged), urine (0.32% mostly metabolites, 0.03% unchanged).

ASSESSMENT
If diarrhea is present, assess for causative organisms and assess if diarrhea is complicated by fever or blood in stool. Assess for hepatic function, pregnancy/nursing status, and possible drug interactions.

MONITORING
Monitor for signs/symptoms of a hypersensitivity reaction, CDAD, development of drug-resistant bacteria, worsening of symptoms, and other adverse reactions.

PATIENT COUNSELING
If being treated for travelers' diarrhea, instruct to d/c therapy and contact physician if diarrhea persists for >24-48 hrs or worsens. Advise to seek medical care for fever and/or blood in the stool. Inform that watery and bloody stools (with or without stomach cramps and fever) may occur even as late as ≥2 months after last dose; advise to contact physician as soon as possible. Inform that drug only treats bacterial, not viral (eg, common cold), infections. Inform that skipping doses or not completing full course of therapy may decrease the effectiveness of treatment and increase resistance. Inform that there is an increase systemic exposure to therapy in patients with severe hepatic impairment (Child-Pugh Class C).

ADMINISTRATION/STORAGE

Administration: Oral route. Take with or without food. **Storage:** 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F).