

Tips for Providers When Counseling Patients About XIFAXAN[®] (rifaximin)

Overt hepatic encephalopathy (OHE) is a complex condition that can be difficult for patients and/or their caregivers to manage. When counseling your patients with OHE, it may help to keep the concept of shared decision making at the forefront of your discussion.

Shared decision making balances your clinical knowledge and expertise with your patient's goals, preferences, beliefs, and cultural values. This process encourages you and your patients to participate in collaborative dialogues that will determine the best way to manage their condition.

Cover the following topics when counseling patients and their caregivers so they have the information they need to help manage their condition.

Medication¹

- XIFAXAN is indicated for the reduction in risk of OHE recurrence in adults.
- XIFAXAN is a nonsystemic antibiotic that slows the growth of bacteria in the gut that are believed to be linked to symptoms of OHE.
 - There is increased systemic exposure in patients with severe hepatic impairment; caution should be exercised when administering XIFAXAN to these patients.
- Take one 550 mg tablet, twice daily—no dose adjustments or titrations needed.
- XIFAXAN can be taken with or without food.
- The most common side effects of XIFAXAN in patients with OHE were peripheral edema, nausea, dizziness, fatigue, and ascites.
- XIFAXAN can be continued for as long as the patient is at risk of recurrent OHE.

Please see additional important safety information below.

When prescribing XIFAXAN, write “XIFAXAN for OHE” to prevent confusion and to ensure the patient, pharmacist, and health plan know why the patient is getting this medication.

Nutrition²

- Weight loss with sarcopenia may worsen HE, so the priority is to eat enough protein and energy to create a positive nitrogen balance and increase in muscle mass.
- Daily energy intakes should be 35-40 kcal/kg ideal body weight.
- Daily protein intake should be 1.2-1.5 g/kg/day.
- Suggest small meals or liquid nutritional supplements evenly distributed throughout the day and a late-night snack.
- The use of a multivitamin is generally recommended.

Monitoring of symptoms²

- Describe early signs of recurring HE to look for (cognitive and motor manifestations).
- Discuss actions to be taken if recurrence happens (eg, anticonstipation measures for mild recurrence).

We don't always know what is running through a patient's head, and we shouldn't presume to know. It is important to always ask patients what their concerns are to determine how to best engage in shared decision making.³

Economic and public social support

- A majority of eligible* commercially insured patients may pay as little as \$0 for XIFAXAN with a copay card.
- Your eligible patients may be entitled to extra help through the Low-income Subsidy program (LIS). LIS recipients are entitled to branded prescription drugs at an affordable cost—no more than \$9.20/prescription, which is a Medicare Part D benefit.⁴

*Patient is not eligible if he/she participates in, seeks reimbursement or submits a claim for reimbursement to any federal or state healthcare program with prescription drug coverage, such as Medicaid, Medicare, Medigap, VA, DOD, TRICARE, or any similar federal or state healthcare program (each a Government Program), or where prohibited by law. Patient must be enrolled in, and must seek reimbursement from or submit a claim for reimbursement to, a commercial insurance plan. Offer excludes full-cash-paying patients. Maximum benefits and other restrictions apply. Visit <https://xifaxan.copaysavingsprogram.com> or call 1-866-XIFAXAN for full eligibility criteria, terms, and conditions.

INDICATION

XIFAXAN[®] (rifaximin) 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults.

IMPORTANT SAFETY INFORMATION

- XIFAXAN is contraindicated in patients with a hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any of the components in XIFAXAN. Hypersensitivity reactions have included exfoliative dermatitis, angioneurotic edema, and anaphylaxis.
- *Clostridium difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including XIFAXAN, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued.
- There is an increased systemic exposure in patients with severe (Child-Pugh Class C) hepatic impairment. Caution should be exercised when administering XIFAXAN to these patients.
- Caution should be exercised when concomitant use of XIFAXAN and P-glycoprotein (P-gp) and/or OATPs inhibitors is needed. Concomitant administration of cyclosporine, an inhibitor of P-gp and OATPs, significantly increased the systemic exposure of rifaximin. In patients with hepatic impairment, a potential additive effect of reduced metabolism and concomitant P-gp inhibitors may further increase the systemic exposure to rifaximin.
- In a clinical study, the most common adverse reactions for XIFAXAN in HE ($\geq 10\%$) were peripheral edema (15%), nausea (14%), dizziness (13%), fatigue (12%), and ascites (11%).
- INR changes have been reported in patients receiving rifaximin and warfarin concomitantly. Monitor INR and prothrombin time. Dose adjustment of warfarin may be required.
- XIFAXAN may cause fetal harm. Advise pregnant women of the potential risk to a fetus.

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please [click here \(http://xifaxan-he-plugin.quicksupportaccess.com/xifaxan-PI\)](http://xifaxan-he-plugin.quicksupportaccess.com/xifaxan-PI) for Full Prescribing Information

References:

1. XIFAXAN [prescribing information] Bridgewater, NJ: Salix Pharmaceuticals. 2. Vilstrup H, Amodio P, Bajaj J, et al. *Hepatic Encephalopathy in Chronic Liver Disease: 2014 Practice Guideline by AASLD and EASL*. Alexandria, VA: American Association for the Study of Liver Diseases; 2014. https://www.aasld.org/sites/default/files/2019-06/141022_AASLD_Guideline_Encephalopathy_4UFd_2015.pdf. Accessed February 18, 2020. 3. Heath S. 3 best practices for shared decision-making in healthcare. <https://patientengagementhit.com/news/3-best-practices-for-shared-decision-making-in-healthcare>. Published September 14, 2017. Accessed January 9, 2020. 4. National Council of Aging (NCOA). Medicare Part D cost saving chart. <https://www.ncoa.org/resources/medicare-part-d-cost-sharing-chart/>. Accessed April 26, 2021.

Content contained in this educational disease-state resource is being provided by Salix Pharmaceuticals for informational purposes only. Physicians should use their own clinical judgment in diagnosing, counseling, and advising patients.