

Xifaxan[®]
rifaximin 550 mg tablets

Hepatic Encephalopathy Case Study

MEET CARLOS

55 years old
Former construction supervisor



Hypothetical patient.

Clinical History

- Cirrhosis secondary to MASLD, diagnosed 2 years ago
- Comorbidities: diabetes, hypertension, obesity, sleep apnea
- Carlos had an overt hepatic encephalopathy (OHE) episode last month and received acute lactulose treatment
- Labs from hospital showed anemia secondary to GI bleed at time of OHE episode
- Discharged from the emergency department with a prescription for lactulose and a note to follow up with his PCP

Reasons for Visit

- Wife notes Carlos has increased fatigue and is more irritable
- Carlos appears forgetful and does poorly on simple memory retrieval tests
- Is no longer able to work and requires assistance with disability paperwork

GI, gastrointestinal; MASLD, metabolic dysfunction-associated steatotic liver disease; PCP, primary care physician.

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

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information.

Management and Referral Plan

- Based on Carlos' previous OHE hospitalization and current symptoms, initiated concurrent XIFAXAN 550 mg twice daily along with lactulose to reduce the risk of OHE recurrence¹
- Referred to gastroenterologist for ongoing management of cirrhosis and HE
- Ordered labs to be performed before gastroenterologist appointment: CBC, CMP, PT/INR, TSH

Patient Education

- Discussed the need to reduce potential precipitating factors, including GI bleeds²
- Reviewed current medications
- Advised on side effects of lactulose and XIFAXAN and need for adherence
- Reviewed XIFAXAN administration information¹
 - Does not require dose adjustments or titrations
 - 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
 - Can be taken with or without food
 - Can be continued for as long as recommended by healthcare provider

CBC, complete blood count; CMP, comprehensive metabolic panel; GI, gastrointestinal; PT/INR, prothrombin time/international normalized ratio; TSH, thyroid-stimulating hormone.

IMPORTANT SAFETY INFORMATION (continued)

- *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.

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Accessing XIFAXAN

- Carlos' commercial insurance covered XIFAXAN
- A prior authorization (PA) was required and approved; to help facilitate approval, the following information was included in the PA submission:
 - ICD-10 code* for OHE diagnosis: K76.82^{3,†}
 - Age: 18 years or older¹
 - Dosing for OHE: #60 XIFAXAN 550-mg tablets, twice daily with refills¹
 - Previous therapies tried and failed (eg, lactulose)
- Carlos was eligible[‡] to use the copay card when picking up his XIFAXAN prescription



*The ICD-10 code and all other patient-access-related information are provided for informational purposes only. It is the treating physician's responsibility to determine the proper diagnosis, treatment, and applicable ICD-10 code. Salix Pharmaceuticals does not guarantee coverage or reimbursement for the product.

[†]ICD-10 code K76.82 excludes patients with hepatic failure with coma (K72.01, K70.41, K72.11, K72.91); use code K72.91 alone in patients with OHE with coma.³



[‡]Maximum benefits and other restrictions apply. Visit xifaxan.copaysavingsprogram.com for full eligibility criteria, terms, and conditions.

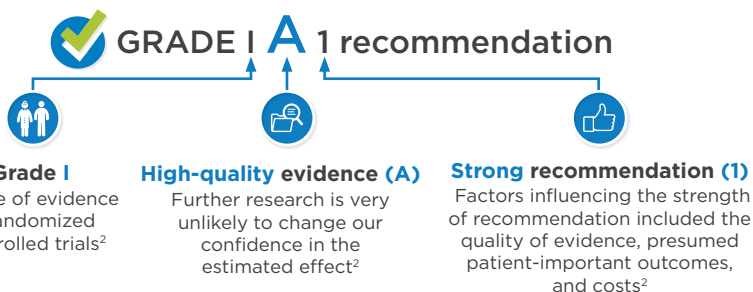
IMPORTANT SAFETY INFORMATION (continued)

- In clinical studies, the most common adverse reactions for XIFAXAN (alone or in combination with lactulose) were:
 - HE (≥10%): Peripheral edema (17%), constipation (16%), nausea (15%), fatigue (14%), insomnia (14%), ascites (13%), dizziness (13%), urinary tract infection (12%), anemia (10%), and pruritus (10%)
- 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 see additional Important Safety Information throughout and [click here](#) for full Prescribing Information.

XIFAXAN earned the highest possible recommendation (GRADE I,A,1) by the AASLD/EASL as an add-on therapy to lactulose to reduce the risk of OHE recurrence after a patient has a recurrence while on lactulose alone.²



AASLD, American Association for the Study of Liver Diseases; EASL, European Association for the Study of the Liver; GRADE, Grading of Recommendation Assessment, Development, and Evaluation.

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Visit [XIFAXAN.com/hcp/he](https://www.salix.com/hcp/he) to learn more about managing OHE recurrence in your adult patients.

References: 1. XIFAXAN. Prescribing information. Salix Pharmaceuticals; 2023. Accessed November 9, 2023. <https://shared.salix.com/globalassets/pi/xifaxan550-pi.pdf> 2. Vilstrup H et al. *Hepatology*. 2014;60(2):715-735. 3. Centers for Medicare & Medicaid Services. 2024 ICD-10-CM tabular list of diseases and injuries. Accessed October 3, 2023. <https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm>