Xifaxan®
rifaximin 550 mg tablets

Hepatic Encephalopathy Case Study

MEET SUSAN

62 years old
Former art gallery owner


Hypothetical patient.

Clinical History

- Cirrhosis secondary to ALD, diagnosed 3 years ago
- Diagnosed with portal hypertension after developing ascites
- Comorbidities: alcohol use disorder, GERD (treated with proton pump inhibitor)
- Susan had an overt hepatic encephalopathy (OHE) episode 3 months ago and is seeking care for improved management
- Prescribed lactulose after hospital discharge

Reasons for Visit

- Requires adult son's assistance since OHE episode
- Son describes Susan as often unable to be independent—she is becoming increasingly confused and disoriented
- Susan shows substantially increased frustration and anger
- Appears malnourished
- Despite prior sobriety, Susan has started consuming alcohol regularly

ALD, alcohol-related liver disease; GERD, gastroesophageal reflux disease.

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.

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Management Plan

- Based on Susan's previous OHE hospitalization and current symptoms, initiated XIFAXAN 550 mg twice daily as an add-on therapy to lactulose to reduce the risk of OHE recurrence[1]
- Ordered labs: CBC, CMP, PT/INR, TSH
- Advised to follow low-sodium Mediterranean diet

Patient Education

- Discussed the need to reduce potential confounding factors, including alcohol use[2]
- Reviewed current medications
- Advised Susan and her son on alcohol cessation methods
- Reviewed XIFAXAN administration information[1]
  - 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; 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

- Susan is dually eligible to receive benefits of both Medicare and Medicaid, which cover 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 older[1]
  - Dosing for OHE: #60 XIFAXAN 550-mg tablets, twice daily with refills[1]
  - Previous therapies tried and failed (eg, lactulose)

100% of Medicare Part D patients have coverage for XIFAXAN[4,‡]

- Dual-eligibility patients may pay as little as $10.35 per script[5]
  - Some low-income patients may qualify for both Medicare and Medicaid. Direct them to healthcare.gov to determine eligibility.

*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]

‡Salix Pharmaceuticals does not guarantee coverage or reimbursement for the product. Formulary status subject to change.

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.

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Xifaxan® rifaximin 550 mg tablets

The Only FDA-Approved Medicine Indicated for the Reduction in Risk of OHE Recurrence in Adults[1]

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]

Grade I
Source of evidence is randomized controlled trials[2]

High-quality evidence (A)
Further research is very unlikely to change our confidence in the estimated effect[2]

Strong recommendation (1)
Factors influencing the strength of recommendation included the quality of evidence, presumed patient-important outcomes, and costs[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 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 costs **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 **4.** Data on file. MMIT September 2023. Salix Pharmaceuticals, Bridgewater, NJ. **5.** Medicare.gov. Help with drug costs. Centers for Medicare & Medicaid Services. Accessed October 19, 2023. https://www.medicare.gov/basics/costs/help/drug-costs

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