Xifaxan®
rifaximin 550 mg tablets

IBS-D Case Study

MEET MARIA

38 years old
Teacher


Hypothetical patient.

Clinical History

- Has suffered with bouts of diarrhea since her mid-20s—blamed it on the stress of her job and raising 3 children
- Initial diet modifications included adding fiber and probiotics
- Previously tried OTC antidiarrheal PRN

Reasons for Visit

- Maria reports loose stools multiple times per week
  - Bristol Stool Form Scale types 6 and 7
- Has experienced abdominal pain associated with diarrhea during the past 9 months
- When questioned about other symptoms, Maria noted that she also experiences bloating when diarrhea occurs
- Maria notes that her symptoms are highly bothersome day-to-day

IBS-D, irritable bowel syndrome with diarrhea; OTC, over-the-counter; PRN, as needed.

INDICATION

XIFAXAN® (rifaximin) 550 mg tablets are indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) 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.

Xifaxan® rifaximin 550 mg tablets

Making a Positive Diagnosis[1]

- Rome IV criteria for IBS-D:
  - Recurrent abdominal pain at least 1 day/week for the last 3 months
  - Associated with 2 or more of the following criteria:
    - Related to defecation
    - Change in frequency of stool
    - Change in form (appearance) of stool
  - Abnormal bowel movements are usually diarrhea
- Alarm features ruled out
  - Colonoscopy recommended with presence of warning signs or if 45 years or older[2]

Diagnosis and Treatment/Referral Plan

- Based on her clinical history and current symptoms, Maria received a diagnosis of IBS-D
- XIFAXAN 550 mg TID for 14 days was initiated for the treatment of IBS-D[3]
  - Maria can be retreated with XIFAXAN up to 2 times if IBS-D symptoms return
- Referred to gastroenterologist for ongoing management
  - Patient was sent with a full lab panel workup

TID, three times daily.

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

- Maria's commercial insurance covered XIFAXAN
- A prior authorization (PA) to confirm indication of IBS-D in an adult patient was required and approved; to help facilitate approval, the following information was included in the PA submission:
  - Indication of IBS-D: ICD-10 code* K58.0[4]
  - Age: 18 years or older[3]
  - Approved dosing for IBS-D: #42 XIFAXAN 550-mg tablets, 3 times a day by mouth for 2 weeks[3]
  - Previous therapies tried and failed (eg, antidiarrheals, antispasmodics, loperamide, SSRIs, TCAs, and other OTC medications)
- Maria was eligible† to use the copay card when picking up her 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.

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

OTC, over-the-counter; SSRI, selective serotonin reuptake inhibitor; TCA, tricyclic antidepressant.

IMPORTANT SAFETY INFORMATION (continued)

- In clinical studies, the most common adverse reactions for XIFAXAN in IBS-D (≥2%) were nausea (3%) and ALT increased (2%).
- 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® rifaximin 550 mg tablets

#1 Prescribed Medication Approved for IBS-D[5,*]

In a US clinical trial, the majority of patients with IBS-D had an abnormal composition of bacteria in the gut[6,†]

- Bacterial imbalance has been linked to multiple IBS-D symptoms[7-9]

XIFAXAN is believed to affect an underlying factor of IBS-D by directly attacking bacteria in the gut that may be linked to IBS-D symptoms[3,6,9-13]

- Blocks one of the steps in transcription of bacterial DNA to RNA
- Inhibits protein synthesis
- Inhibits bacterial growth

The mechanism of action of XIFAXAN is unknown and does not imply clinical efficacy.

*Based on aggregated total of all prescribers as of June 2023.
†Data from 93 patients with IBS-D in a prospective TARGET 3 substudy that used lactulose breath testing to predict response to XIFAXAN.

XIFAXAN is a 2-week treatment[3]

- One 550-mg tablet 3 times daily for 14 days
- Patients who experience recurrence can be retreated up to 2 times

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Visit XIFAXAN.com/hcp/ibsd to get your adult patients with IBS-D started on XIFAXAN.

References: 1. Lacy BE et al. *Gastroenterology.* 2016;150(6):1393-1407. **2.** Lacy BE et al. *Am J Gastroenterol.* 2021;116(1):17-44. **3.** XIFAXAN. Prescribing information. Salix Pharmaceuticals; 2023. Accessed November 15, 2023. https://shared.salix.com/globalassets/pi/xifaxan550-pi.pdf **4.** 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 **5.** Data on file: LAAD June 2023. Salix Pharmaceuticals, Bridgewater, NJ. **6.** Rezaie A et al. *Am J Gastroenterol.* 2019;114(12):1886-1893. **7.** Pimentel M et al. *N Engl J Med.* 2011;364(1):22-32. **8.** Sundin J et al. *Sci Rep.* 2020;10(1):593. **9.** Zhong W et al. *J Clin Gastroenterol.* 2019;53(9):660-672. **10.** Debbia E et al. *J Chemother.* 2008;20(2):186-194. **11.** Fodor AA et al. *Gut Microbes.* 2019;10(1):22-33. **12.** Soldi S et al. *Clin Exp Gastroenterol.* 2015;8:309-325. **13.** Zeber-Lubecka N et al. *Gut Microbes.* 2016;7(5):397-413.

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