DOCTOR/PATIENT DISCUSSION GUIDE FOR PEOPLE WITH PBC ITCH (CHOLESTATIC PRURITUS)



What is PBC itch (cholestatic pruritus)?



PBC itch is a specific type of itching that occurs in people with PBC. Although the pathophysiology of PBC itch in people with PBC is not completely understood, it is believed to be caused by a buildup of bile acids in the body, which can trigger intense itching.



How common is cholestatic pruritus? Most people with PBC experience cholestatic pruritus at some point. If you have PBC and experience persistent itching, you're not alone, and it's important to discuss your symptoms with your doctor.



Why mention it to your doctor? PBC itch can significantly affect your sleep, work, and social activities, as well as your overall well-being. Yet, many people with PBC don't discuss it with their doctors or even realize it can be treated.

PBC=primary biliary cholangitis.

Speaking up may help your doctor provide better care.

UNDERSTANDING AND COMMUNICATING YOUR ITCH SYMPTOMS

Being clear and specific about your symptoms helps your doctor find the right treatment for you. Before your appointment, think about the following 5 key areas:

1. How often are you itching?

Think about the past 2 weeks:

☐ Less than 6 hours per day ☐ 6 to 12 hours per day ☐ 12 to 18 hours per day ☐ 18 to 23 hours per day

☐ All day and all night

2. How intense is your itching?

Rate your itching intensity over the past 2 weeks:

☐ Not present ☐ Mild (annoying but manageable) ☐ Moderate (difficult to ignore) ☐ Severe (unbearable at times)

☐ Unbearable (affects everything I do)

3. Is your itching worse during the day or night?

☐ Day ☐ Night

4. How is itching affecting your sleep?

Rate its impact over the past 2 weeks (Never / Rarely / Occasionally / Frequently / Always):

Has your itching delayed you from falling asleep or kept you up at night?

☐ Never ☐ Rarely ☐ Occasionally ☐ Frequently ☐ Always

Has itching affected you in any other ways? _____

_____

5. Where on your body do you itch?

Check all areas where you've experienced itching over the past 2 weeks:

☐ Head/Scalp ☐ Face ☐ Chest ☐ Arms ☐ Hands/fingers ☐ Stomach ☐ Back ☐ Thighs ☐ Legs ☐ Feet/toes

☐ Points of contact with clothing (waistband, undergarments, etc) ☐ Groin

HOW TO START A CONVERSATION WITH YOUR DOCTOR

Tip

Schedule a focused appointment or call your doctor ahead of time to let them know you want to discuss your itching. This gives them time to prepare and **helps ensure** you have adequate time to talk.

Suggested opening:

"I've been experiencing relentless itching that is significantly affecting my life. After doing some research, I believe it may be cholestatic pruritus, which is common among people with PBC like me. I've kept track of my symptoms in hopes to help with this conversation."

Share the following with your doctor:

- Your answers from page 2
- Current treatments you've tried and whether they've helped

Lynavoy
(linerixibat)
40 mg tablets

THE FIRST AND ONLY FDA-APPROVED MEDICATION FOR CHOLESTATIC PRURITUS (ITCH) IN PEOPLE WITH PBC

What is LYNAVOY?

- LYNAVOY is a prescription medicine used to treat itching (pruritus) in adults with primary biliary cholangitis (PBC).
- LYNAVOY is not for use in people with severe liver disease (decompensated cirrhosis), or people who have or have had certain liver-related problems including bleeding of enlarged blood vessels in the stomach-area (variceal hemorrhage), fluid in the stomach-area (ascites), or nervous system problems (such as confusion, slurred speech, sluggish movements) caused by severe liver disease (hepatic encephalopathy).
- It is not known if LYNAVOY is safe and effective in children.

In a clinical trial, LYNAVOY was shown to:

Reduce itching over 24 weeks

- **LYNAVOY** improved itch by **2.86 points**
- **Placebo** improved itch by **2.15 points**
- On average, **study participants treated with LYNAVOY reduced itch from a score of 7.33 to 3.80** vs placebo (7.36 to 4.52)
- At Week 2, **LYNAVOY reduced itch more than placebo**

Improve sleep over 24 weeks

- **LYNAVOY** improved sleep score by **2.77 points**
- **Placebo** improved sleep score by **2.24 points**
- **LYNAVOY showed a greater improvement in itch-related sleep interference,** with an additional improvement of **0.53 points** compared to placebo

GLISTEN: LYNAVOY clinical trial design over 24 weeks

- 238 people with PBC itch; Age range: 30-80 years; 97% taking UDCA; 47% taking other itch-relief medications
- Half of people received LYNAVOY (119 people), half received placebo (118 people)
- Itch relief: People rated their worst itch on a scale from 0 (no itching) to 10 (worst imaginable itching). The average starting itch score was 7.3
- Sleep relief: People rated how much itching interfered with sleep on a scale from 0 (no sleep interference) to 10 (completely interfered with sleep). The average starting sleep interference score was 6.3
- The most common side effects were diarrhea (62% of people) and stomach pain (26% of people)
- 14% of people treated with LYNAVOY and 5% of people treated with placebo stopped treatment due to side effects

GLISTEN=Global Linerixibat Itch STudy of Efficacy and Safety iN primary biliary cholangitis; UDCA=ursodeoxycholic acid.

IMPORTANT SAFETY INFORMATION

Before using LYNAVOY, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if LYNAVOY will harm your unborn baby.

Please see additional Important Safety Information on page 5 and full Prescribing Information for LYNAVOY or at LYNAVOY.com.

Questions to consider asking your doctor:

- *"Based on my symptoms, could LYNAVOY help reduce my PBC itch?"*
- *"How does LYNAVOY work?"*
- *"How soon may I notice improvement in my itch while taking LYNAVOY?"*
- *"How often should I take LYNAVOY?"*
- *"What side effects should I watch out for when taking LYNAVOY?"*
- *"Where can I learn more about LYNAVOY?"*

IMPORTANT SAFETY INFORMATION (cont'd)

Before using LYNAVOY, tell your healthcare provider about all of your medical conditions, including if you (cont'd):

- **Pregnancy Safety Study:** Pregnancy outcomes in women who become pregnant while using LYNAVOY is being collected. The purpose of this is to collect information about your health and your baby's health. You or your healthcare provider should report your pregnancy by calling 1-844-782-4278.
- are breastfeeding or plan to breastfeed. It is not known if LYNAVOY passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while using LYNAVOY.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. LYNAVOY and certain other medicines may interact with each other. Especially tell your healthcare provider if you take:

- **bile acid binding resins** (used to reduce absorption of bile acids from the intestine), such as cholestyramine or colesevelam. These may reduce the effects of LYNAVOY. If you take any of these medicines, take LYNAVOY at least **4 hours before or 4 hours after** taking a bile acid binding resin.

What are the possible side effects of LYNAVOY?

LYNAVOY may cause serious side effects, including:

- **Increased liver enzymes.** An increase in liver enzymes (liver-related blood tests) can happen in people who use LYNAVOY and can be serious. Your healthcare provider will do blood tests to check your liver before starting treatment and during treatment with LYNAVOY. Your healthcare provider may need to stop your treatment with LYNAVOY because of an increase in liver enzymes.
- **Diarrhea.** Diarrhea can happen in people who use LYNAVOY and can be serious. Diarrhea can cause a loss of body fluid (dehydration). Check for signs of dehydration including thirst, dry mouth, urinating less often, or headache. Call your healthcare provider if you have diarrhea that does not go away.
- **Fat-Soluble Vitamin (FSV) Deficiency.** A condition called FSV deficiency caused by low levels of certain vitamins (vitamin A, D, E, and K) stored in body fat, can happen with LYNAVOY. Your healthcare provider will do blood tests for FSV deficiency before starting and during treatment with LYNAVOY. People with FSV deficiency can bleed more easily or bleed longer or may develop bone fractures. Call your healthcare provider if you have bleeding problems or a bone fracture while using LYNAVOY.
- **The most common side effects of LYNAVOY include:**
  - diarrhea
  - stomach pain
  - nausea
  - bleeding
  - increased liver enzymes (ALT, AST)
  - headache
  - upset stomach
  - gastroesophageal reflux disease
  - stomach bloating
  - dizziness
  - joint pain

These are not all the possible side effects of LYNAVOY. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see additional Important Safety Information on page 5 and full Prescribing Information for LYNAVOY or at LYNAVOY.com.

Lynavoy
(linerixibat)
40 mg tablets

Visit LYNAVOY.com to learn more.

ALFASIGMA

©2026 Intercept Pharmaceuticals, Inc. All rights reserved. LYNAVOY is a trademark of the GSK Group of Companies and is licensed to Intercept Pharmaceuticals, Inc., a wholly owned subsidiary of Alfasigma S.p.A.
US-PP-CP in PBC-0080-2 09/26