Descargar el folleto **en español.**

Lynavoy
(linerixibat)
40 mg tablets

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

Cholestatic pruritus, also known as PBC itch, affects most people with PBC. It can be a persistent, debilitating itch associated with the liver disease.



Previously, there were no FDA-approved medications to treat PBC itch. **LYNAVOY is specially designed to treat PBC itch.**

PBC = primary biliary cholangitis.

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.

IMPORTANT SAFETY INFORMATION

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

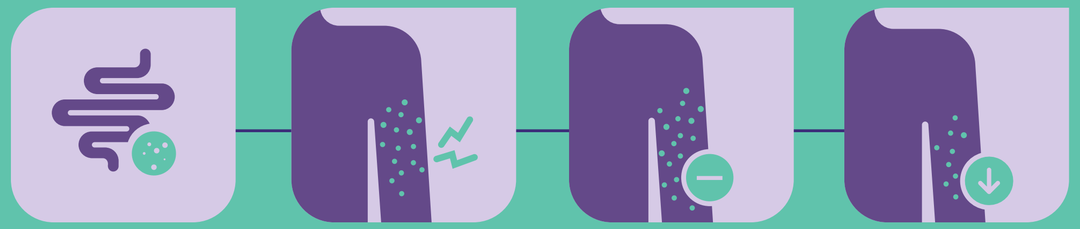
- are pregnant or plan to become pregnant. It is not known if LYNAVOY will harm your unborn baby.

Please see additional Important Safety Information throughout and full Prescribing Information for LYNAVOY at LYNAVOY.com.

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HOW DOES LYNAVOY WORK?

LYNAVOY helps reduce bile acid levels in the body.



The small intestine normally reabsorbs bile acids, initially produced in the liver, so they can be used again.

In people with PBC, bile acids can build up in the blood and be a root cause of itching.

LYNAVOY blocks this reabsorption process to allow more bile acids to leave the body.

LYNAVOY helps reduce the bile acids associated with PBC itch.

- The cause of itch in people with PBC is not completely understood
- Exactly how LYNAVOY works to treat PBC itch is not fully understood

IMPORTANT SAFETY INFORMATION (cont'd)

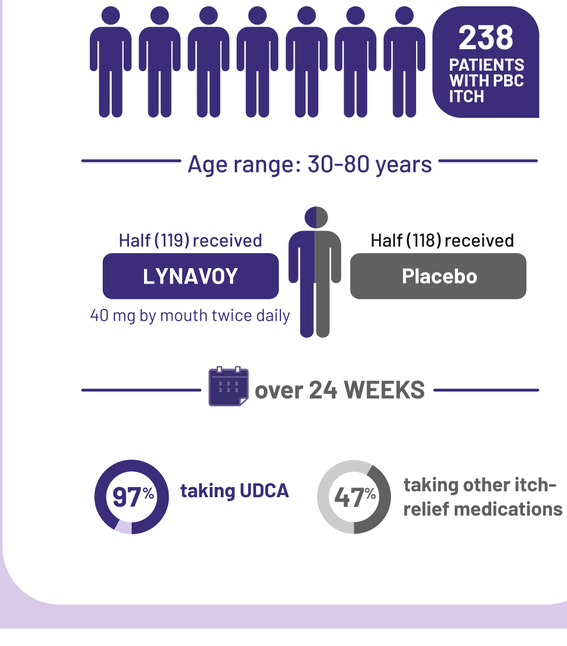
Before using LYNAVOY, tell your healthcare provider about all of your medical conditions, including if you (cont'd):

- **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.

HOW WAS LYNAVOY STUDIED?

GLISTEN: LYNAVOY clinical trial design

This trial was a double-blind study, meaning neither study participants nor doctors knew who was getting LYNAVOY. In general, this helps reduce bias in clinical studies.



GLISTEN = Global Linerixibat Itch Study of Efficacy and Safety in Primary Biliary Cholangitis; UDCA = ursodeoxycholic acid.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Please see additional Important Safety Information throughout and full Prescribing Information for LYNAVOY at LYNAVOY.com.

HOW DID LYNAVOY PERFORM IN THE CLINICAL TRIAL?

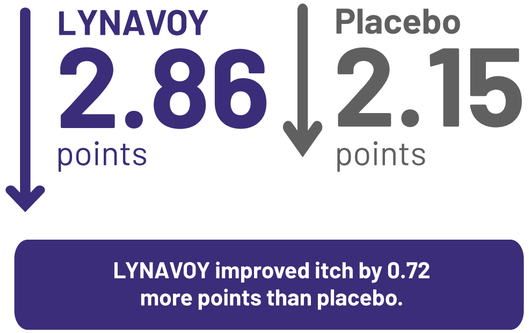


Itch relief

In the GLISTEN study, participants rated their worst itch on a scale from 0 (no itching) to 10 (worst imaginable itching). The average starting itch score was 7.3.

Over 24 weeks:

- **LYNAVOY** improved itch by **2.86 points** (nearly 3 points on the 0-10 scale)
- **Placebo** improved itch by **2.15 points**
- **LYNAVOY showed a greater improvement in itch,** with an additional improvement of **0.72 points** compared to placebo
- This difference was **statistically significant**, meaning it was very unlikely to be due to chance
- On average, **people 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



Rapid itch relief as early as 2 weeks.
Sustained itch relief through 24 weeks.

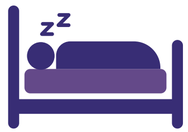
IMPORTANT SAFETY INFORMATION (cont'd)

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.

HOW DID LYNAVOY PERFORM IN THE CLINICAL TRIAL?

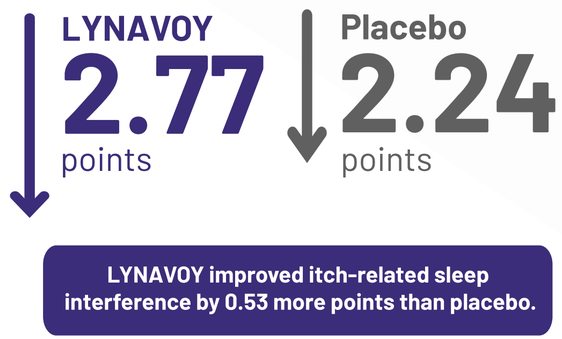


Sleep relief

The GLISTEN study also measured how much itching interfered with sleep, using a scale from 0 (no sleep interference) to 10 (completely interfered with sleep). The average starting sleep interference score was 6.3.

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
- This difference was **statistically significant**



People taking LYNAVOY significantly improved itch-related sleep interference compared to placebo over 24 weeks.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of LYNAVOY? (cont'd)

- **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.

Please see additional Important Safety Information throughout and full Prescribing Information for LYNAVOY at LYNAVOY.com.

LYNAVOY SAFETY

Common side effects

This table shows the side effects occurring in ≥5% of people treated with LYNAVOY and occurring more frequently in LYNAVOY group, in the GLISTEN study.

Side Effect	LYNAVOY	Placebo
Diarrhea	62%	18%
Stomach pain	26%	10%
Nausea	10%	9%
Bleeding	9%	3%
Headache	8%	3%
Liver enzymes increased (ALT, AST)	8-9%	<1-3%
Upset stomach	8%	<1%
Gastroesophageal reflux disease	7%	4%
Stomach bloating	7%	5%
Dizziness	6%	3%
Joint pain	6%	5%

- Most diarrhea events occurred within the first 20 days of initiating treatment. Of the people who experienced diarrhea, 96% of them had mild or moderate cases
- 14% of people treated with LYNAVOY and 5% of people treated with placebo stopped treatment due to side effects (eg, diarrhea, stomach pain, and liver enzyme increases)

While you are taking LYNAVOY, your doctor will continue to monitor your liver.

Talk to your doctor if you experience any side effects.

HOW SHOULD YOU TAKE LYNAVOY?

Always take LYNAVOY exactly as your healthcare provider tells you.

Take 1 tablet by mouth twice daily, once in the morning, and once in the evening

Swallow the tablet whole with some water, at least 30 minutes before any food or beverage (other than water)

If you take a bile acid binding resin, such as cholestyramine or colesevelam, **take it at least 4 hours before or after taking LYNAVOY.**

If you miss a dose, take it as soon as possible and at least 30 minutes before your next meal.

If a dose is missed by more than 6 hours, skip the dose, and take the next dose at the regular time.

Do **NOT** take a double dose to make up for a missed dose.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of LYNAVOY? (cont'd)

- **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.

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Interconnect®

YOUR PRESCRIPTION SUPPORT

Interconnect Care Managers can explore financial assistance options for you, including a co-pay program that may help you get your prescribed LYNAVOY for as little as $0* per month. And that's just the beginning. Interconnect also provides personalized support and education every step of the way.

Three ways your Care Manager can help

1 Coverage assistance

Care Managers can help you understand your current benefits and explore other coverage assistance options, including a program that can help you get LYNAVOY for as little as a $0 co-pay* per month.

2 Getting started

Once you and your healthcare provider decide that LYNAVOY is right for you, a Care Manager will be in touch to guide you through the process of getting started with treatment.

3 Treatment support and education

A Care Manager will be here to help you get the resources you need—both at the outset and on an ongoing basis.

You may be able to get your monthly LYNAVOY prescription for as little as $0*

Call your Interconnect Care Manager at 1-844-622-4278

* Except where prohibited by law. Some people will not qualify for certain service offerings. Intercept reserves the right to rescind, revoke, or amend this offer without notice. For full terms and conditions of the co-pay program, visit interconnectsupport.com/en/copay-terms.

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

In a clinical trial, LYNAVOY was shown to:

Reduce Itching:
LYNAVOY significantly reduced itch severity compared to placebo over 24 weeks of treatment

Improve Sleep:
Patients taking LYNAVOY **experienced greater improvement in itch-related sleep interference** compared to those taking placebo over 24 weeks

Talk to your doctor if you have any questions about your LYNAVOY prescription.

The most common side effects were:

- **Diarrhea** (62% of patients)
- **Stomach Pain** (26% of patients)

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of LYNAVOY? (cont'd)

- **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.

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  - nausea
  - bleeding
  - increased liver enzymes (ALT, AST)
  - headache
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NOTES

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