

PATIENT INFORMATION

LYNAVOY [LIN-ah-voy]

(linerixibat)

tablets, for oral use

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.

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.
 - **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.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use LYNAVOY?

- Always take LYNAVOY exactly as your healthcare provider has told you to. Check with your healthcare provider if you are not sure.
- Take 1 LYNAVOY tablet by mouth 2 times each day (1 tablet in the morning and 1 tablet in the evening).
- Swallow the tablet whole with some water.
- Take LYNAVOY **at least 30 minutes** before you have any food or drink (except water).
- If you take a bile acid binding resin such as cholestyramine or colesevelam, take it at least 4 hours before or 4 hours after taking LYNAVOY.
- **If you miss a dose of LYNAVOY, take it as soon as possible and at least 30 minutes before your next meal. If more than 6 hours have passed, skip the missed dose and take the next dose at the regular time. Don't take a double dose** to make up for a missed dose.
- If you take too much LYNAVOY, call your healthcare provider, Poison Help line at 1-800-222-1222, or go to the nearest hospital emergency room right away.

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 as needed 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.

How should I store LYNAVOY?

- Store LYNAVOY at room temperature between 20° to 25°C (68° to 77°F), in the original package to protect from moisture.
- Keep the bottle tightly closed.
- LYNAVOY bottles contain a desiccant canister (drying agent) to help keep the medicine dry. Do not remove or swallow the desiccant canister.

Keep LYNAVOY and all medicines out of the reach of children.

General information about the safe and effective use of LYNAVOY.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use LYNAVOY for a condition for which it was not prescribed. Do not give LYNAVOY to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about LYNAVOY that is written for health professionals.

What are the ingredients in LYNAVOY?

Active ingredients: linerixibat 40 mg

Inactive ingredients: croscarmellose sodium, magnesium stearate and microcrystalline cellulose.

Tablet film-coating: black iron oxide, hypromellose, polyethylene glycol, red iron oxide, and titanium dioxide.

For more information about LYNAVOY, call 1-844-782-4278 or visit our website at www.lynavoy.com. LYNAVOY is a trademark of GSK Group of Companies licensed to Intercept Pharmaceuticals, Inc.

Manufactured for:

Intercept Pharmaceuticals, Inc., a wholly owned subsidiary of Alfasigma S.p.A. Morristown, NJ 07960

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