



40 mg film-coated tablets
linerixibat

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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1 What Lynavoy is and what it is used for

Lynavoy contains the active ingredient linerixibat. Linerixibat increases the removal of *bile acids* from the body through bowel movements (stool). Bile acids are part of the digestive fluid. They are produced by the liver and released into the gut to help digest your food.

Lynavoy is used to treat itch (*pruritus*) in adults with primary biliary cholangitis (PBC). PBC is a condition where bile ducts in the liver become damaged, leading to a build-up of bile acids in the blood. This build-up is thought to cause itching. Lynavoy helps to reduce the build-up of substances, including bile acids, in your body, and so reduce itching.

2 What you need to know before you take Lynavoy

Do not take Lynavoy

- if you are **allergic** to linerixibat or any of the other ingredients of this medicine (listed in section 6).

→ **Check with your doctor** before taking Lynavoy if you may be **allergic** to any of its ingredients.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lynavoy. Before starting Lynavoy, your doctor will do blood tests to assess the health of your liver. Lynavoy may not be suitable for you if you have severe liver disease.

While you are taking Lynavoy

- you may develop **diarrhoea**, which is a very common side effect of Lynavoy (see section 4, 'Possible side effects'). Talk to your doctor or pharmacist if you develop diarrhoea that interferes with your daily activities while taking Lynavoy.
- taking Lynavoy may change the results of your blood tests for liver function. Your doctor will do regular **blood tests** to monitor your liver function and manage your treatment accordingly.

Children and adolescents

Do not give Lynavoy to children and adolescents under 18 years of age, as it is not known if the medicine is safe and effective in this age group.

Other medicines and Lynavoy

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor about all the medicines you take including:

- **bile acid binding resins** (used to reduce absorption of bile acids from the intestine), such as **colestyramine**, **colesevelam**, or **colestipol**. 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.
 - **obeticholic acid** (used to treat PBC). Lynavoy may reduce the effects of obeticholic acid.
- If you need more advice, talk to your doctor, pharmacist or nurse.

You can take **ursodeoxycholic acid** ('urso') while you are taking Lynavoy, and your dose will not normally need to be changed.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby:

→ **Talk to your doctor** or pharmacist for advice before taking this medicine.

Lynavoy has not been studied in pregnant or breast-feeding women. If you become pregnant during treatment with Lynavoy

→ **Tell your doctor.**

It is not known if the active substance of Lynavoy is passed into human breast milk. Your doctor will advise you if you can breast-feed during your treatment or if you should interrupt breast-feeding or treatment.

Driving and using machines

Lynavoy is not expected to affect your ability to drive or use machines.

Lynavoy contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 How to take Lynavoy

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of Lynavoy is one tablet taken twice a day (one in the morning and one in the evening).

Lynavoy is a tablet that is taken by mouth. Swallow the tablet whole, with some water, as follows.

- Take Lynavoy **on an empty stomach**, except for water, which you can drink any time as needed (but no other drink)
- After taking Lynavoy, leave about **30 minutes before** you have **any food or drink** (except water).

If you also need to take a bile acid binding resin (such as colestyramine, colesevelam, or colestipol):

- take it at least **4 hours before** or **4 hours after** you take Lynavoy (see also 'Other medicines and Lynavoy' in section 2).

Do not remove or swallow the desiccant canister found in the bottle (see 'What Lynavoy looks like and contents of the pack' in section 6).

If you take more Lynavoy than you should

If you take too many tablets of Lynavoy, contact your doctor or pharmacist for advice. The most likely effects of taking too much Lynavoy are diarrhoea and stomach pain.

If you forget to take Lynavoy

Do not take a double dose to make up for a forgotten tablet. Take the missed dose as soon as you remember. Then continue taking your tablet at regular times as usual. If you are not sure what to do, ask your doctor or pharmacist.

If you stop taking Lynavoy

Take Lynavoy for as long as your doctor recommends. Don't stop unless your doctor advises you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects

- (may affect more than 1 in 10 people)
- diarrhoea
 - stomach pain

Common side effects

- (may affect up to 1 in 10 people)
- increases in substances (*enzymes*) produced by the liver (ALT, AST), which show up in blood tests

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Lynavoy

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the package and bottle label after EXP. The expiry date refers to the last day of that month.

Keep the bottle tightly closed and keep in the outer carton to protect from moisture.

The bottle contains a plastic desiccant canister. Keep the desiccant in the bottle to protect the tablets from moisture. Do not swallow the desiccant.

This medicine does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Lynavoy contains

The active substance is linerixibat. Each film-coated tablet contains 40 mg linerixibat.

The other ingredients are:

- Tablet core: microcrystalline cellulose (E 460), croscarmellose sodium (E 468), magnesium stearate (E 470b).

- Film-coating: hypromellose (E 464), titanium dioxide (E 171), macrogol (E 152), iron oxide black (E 172), iron oxide red (E 172).

See 'Lynavoy contains sodium' in section 2 for more information about the amount of sodium in Lynavoy tablets.

What Lynavoy looks like and contents of the pack

Lynavoy 40 mg tablets are purple, round, biconvex film-coated tablets (9 mm in diameter) with "GS 3JG" marked on one side.

Lynavoy is available in bottles of 60 film-coated tablets, or as multipacks containing 3 bottles of 60 film-coated tablets (180 film-coated tablets).

The bottles contain a plastic desiccant canister to protect the tablets from moisture. Once the bottle has been opened, keep the desiccant in the bottle. Do not remove the desiccant and do not swallow it.

Not all pack sizes may be marketed.

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Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	Lynavoy 40 mg film-coated tablets
Reference number	PL 19494/0330

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