



LIVDELZI[®] (seladelpar)

What are the possible side effects of LIVDELZI?

This information is provided in response to your question. It is not treatment advice on how to use **LIVDELZI**. Please discuss this question and others you have about your medical condition or treatment with your healthcare provider.

Download the **LIVDELZI Patient Information** for more details, including approved use(s) and important warnings: https://www.gilead.com/-/media/files/pdfs/medicines/pbc/livdelzi/livdelzi_patient_pi.pdf

The short answer¹

In the main study, **the most common side effect** of LIVDELZI was **headache**. Headache happened in 8% of people, which is 8 in every 100 people.

LIVDELZI may cause **serious side effects** such as:



Breaks or cracks in your bones, also called fractures. LIVDELZI can increase your chance of breaking a bone.



Changes in liver tests. Taking more LIVDELZI than what your healthcare provider tells you can increase liver enzymes in the blood.

These are not all the possible side effects of LIVDELZI. Please tell your healthcare provider if you have any side effects.

Who is LIVDELZI for?¹

LIVDELZI is a prescription medicine used to **treat primary biliary cholangitis, or PBC, in adults**. It is approved for use with another medicine for PBC called UDCA in people who have not responded well. It is also approved for use alone if UDCA could not be tolerated.



People with advanced liver disease, also called decompensated cirrhosis, should not take LIVDELZI. Symptoms may include:

- confusion
- having fluid in the stomach area
- black, tarry, or bloody stools
- coughing up blood
- blood in vomit or vomit that looks like “coffee grounds”

It is not known if LIVDELZI will prevent advanced liver disease or improve your chance of staying alive.

It is not known if LIVDELZI works well or is safe in children.

What are the common side effects of LIVDELZI?¹

The most **common side effects** of LIVDELZI in the main study were:

- **headache**
- **stomach pain**
- **nausea**
- **stomach bloating or swelling**
- **dizziness**

Headache happened in 8% of people, which is 8 in every 100 people. The other common side effects each happened in no more than 7% of people who took LIVDELZI.

These are not all of the possible side effects of LIVDELZI.

What are the serious side effects of LIVDELZI?¹

LIVDELZI may cause **serious side effects** such as:



- **Breaks or cracks** in your bones, also called bone fractures. LIVDELZI can increase your chance of breaking a bone.

Tell your healthcare provider right away if you:

- break a bone
- have pain
- have changes in how you move around.



- **Changes in liver tests.** Taking more LIVDELZI than what your healthcare provider tells you can increase liver enzymes in the blood. Your healthcare provider will do tests to check your liver before you start and while taking LIVDELZI.

Tell your healthcare provider right away if you have signs of liver problems such as:

- swelling in your stomach area from fluid build up
- the skin or the white part of the eyes turning yellow
- pain on the right side of your stomach
- black, tarry, or bloody stools
- coughing up blood
- blood in vomit or vomit that looks like “coffee grounds”
- mental changes such as confusion, slurred speech, mood swings, change in personality, sleepier than usual, or harder to wake up.

These are not all of the possible side effects of LIVDELZI.

Contact your healthcare provider right away if you are concerned about any symptoms you are having or if you think that you might have any of these side effects.

What should I tell my healthcare provider before taking LIVDELZI?¹

Before taking LIVDELZI, tell your healthcare provider about all your medical conditions, including if you:



- **have advanced liver disease**



- **think you may have blocked bile ducts in your liver**



- **are breastfeeding or plan to breastfeed.** It is not known if LIVDELZI passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby.



- **are pregnant or plan to become pregnant.** It is not known if LIVDELZI will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking LIVDELZI.



Pregnancy Safety Study: Tell your healthcare provider right away if you become pregnant while taking LIVDELZI. There is a study looking at the safety of LIVDELZI in people who are pregnant. The goal of the study is to collect information on your health and your baby's health. Talk to your healthcare provider about how you can take part in the study. **You or your healthcare provider can report pregnancy by calling 1-800-445-3235.**

What should I tell my healthcare provider about the medicines I take before taking LIVDELZI?¹

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.



LIVDELZI can affect the way some medicines work.
Also, some medicines may affect how LIVDELZI works.

Talk with your healthcare provider before starting a new medication.

Glossary

Bile ducts: tubes that carry bile between some organs in your body such as the liver. Bile helps to break down fats in the food you eat.

Decompensated cirrhosis: when the liver is so damaged that it can no longer work.

Nausea: feeling sick to the stomach; stomach discomfort and the feeling of wanting to vomit.

Primary biliary cholangitis or PBC: when your immune system attacks the bile ducts in your liver. The ducts become swollen, and over time can become blocked. Bile can back up into your liver and that causes damage.

Ursodeoxycholic acid or UDCA: is a type of medicine to treat PBC. It helps clear bile from the liver.

Reference

1. Livdelzi Gilead Sciences Inc. LIVDELZI® (seladelpar) capsules, for oral use. US Prescribing Information. Foster City, CA. Revised August. 2024.

More information about LIVDELZI

If you would like more detailed information about LIVDELZI, please visit:

https://www.gilead.com/-/media/files/pdfs/medicines/pbc/livdelzi/livdelzi_pi.pdf

This is the US FDA-approved Prescribing Information, including the Patient Labeling, for LIVDELZI. It will tell you about the uses, warnings, and other important safety information about LIVDELZI.

Important note

Gilead Sciences, Inc. is providing this letter in response to your unsolicited request for medical information. Some of the information included in this letter may not be covered in the US FDA-approved Prescribing Information for LIVDELZI. Gilead Sciences, Inc. does not intend this letter to be used as medical advice and does not promote use of LIVDELZI in a way that has not been approved by the FDA. Please discuss this question and others you may have about your medical condition or treatment with your healthcare provider.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎ 1-866-MEDI-GSI (1-866-633-4474) or 📧 <https://www.patient.askgileadmedical.com/>

Reporting side effects

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or

📧 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 📧 www.accessdata.fda.gov/scripts/medwatch

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