



LIVDELZI® (seladelpar)

What should I know about fractures while taking 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_pi

The short answer¹



Taking LIVDELZI may increase your risk of bone fractures. **Tell your healthcare provider about any bone fractures, or if you develop pain, or if you have changes in your ability to move around.**

If you're taking LIVDELZI, it is important to think about the risk of broken bones. Make sure to have your bone health checked regularly, following your doctor's advice.



Four percent (4%) of people who were treated with LIVDELZI experienced fractures.

Who is LIVDELZI for?¹



LIVDELZI is a prescription medicine used to treat **primary biliary cholangitis (PBC)** in combination with ursodeoxycholic acid (UDCA) in

adults who have not responded well to UDCA or used alone in people unable to tolerate UDCA.



LIVDELZI is **not recommended for use in people who have advanced liver disease** (decompensated cirrhosis). Symptoms of advanced liver disease may include confusion; having fluid in the stomach-area (abdomen); black, tarry, or bloody stools; coughing up or vomiting blood, or having vomit that looks like “coffee grounds”.

- It is not known if taking LIVDELZI will improve your chance of survival or prevent liver decompensation.
- It is not known if LIVDELZI is safe and effective in children.

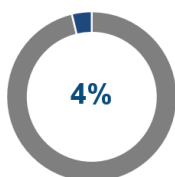
Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. LIVDELZI can affect the way certain medicines work. Certain other medicines may affect the way LIVDELZI works.

How should I take LIVDELZI?¹

- Take LIVDELZI exactly as your doctor tells you to.
- **Do not take more LIVDELZI than your healthcare provider tells you to.**
- Take LIVDELZI **by mouth 1 time each day.**
- Take LIVDELZI **with or without food.**
- **If you take too much LIVDELZI, call your healthcare provider or get emergency medical help right away.**
- If you also take medicines to help lower your cholesterol (bile acid binding resins), **take LIVDELZI at least 4 hours before or 4 hours after you take the bile acid binding resin.** If this is not possible, space the time between taking LIVDELZI and your bile acid binding resin as far apart as possible.

Did patients have fractures during clinical trials?

Details from the RESPONSE study¹⁻³



In one study called RESPONSE, people with primary biliary cholangitis were given either LIVDELZI or a placebo (a pill that contains no medicine). There were 128 people treated with LIVDELZI. **Four percent (4%)** or 5 people who were treated with LIVDELZI experienced fractures.

There were 65 people treated with placebo. **None (0%)** of the people who took placebo experienced fractures.

What types of fractures did the patients have?



- One fracture happened because of a car accident.
- Two fractures were caused by fragility fractures or weak bones: One person had osteoarthritis (which is a joint disease that can cause pain and stiffness) and osteoporosis (which is the softening of the bones) and the other person had low vitamin D and had recently broken their arm.
- The two other fractures were in people with osteopenia (low bone density).

Did people have fractures before they took LIVDELZI?



What is a risk factor?

A risk factor is something that makes it more likely that something bad will happen.

At the beginning of the study people who were treated with LIVDELZI and those who were treated with a placebo were noticed to have different risk factors for fractures.

Table 1 below shows a list of risk factors for fractures among the people in the study before it began.

Table 1. RESPONSE Study: Baseline Characteristics about Fracture Risk Factors

Baseline Characteristics	LIVDELZI* (n=128)	Placebo (n=65)
Vitamin D Deficiency	18%	5%
Osteoporosis	14%	8%
Osteoporosis medication	6%	3%
Osteopenia	13%	12%

n = the number of patients
Deficiency = lack of
Osteopenia = low bone density but not low enough to be classed as osteoporosis.
Osteoporosis = softening of the bones.

Glossary

Abdomen: belly; stomach.

Arthritis: painful inflammation and stiffness of the joint.

Baseline: the initial time point in a clinical trial that provides a basis for assessing changes in subsequent assessments or observations. At this reference point, measurable values such as physical exam, laboratory tests, and outcome assessments are recorded.

Biliary Cholangitis: swelling of the bile ducts.

Cirrhosis: scarring of the liver; Cirrhosis is a late stage of scarring (fibrosis) of the liver caused by many forms of liver diseases and conditions, such as hepatitis and chronic alcoholism.

Decompensated: reduced functioning of an organ.

Liver Decompensation: reduced function of the liver.

Osteoarthritis: most common form of arthritis, also called degenerative joint disease or "wear and tear" arthritis; painful and stiff joints disease.

Osteopenia: low bone density but not low enough to be classed as osteoporosis.

Osteoporosis: softening of the bones.

Placebo: a pill that contains no medicine; In a clinical trial, a placebo is made to look like the investigational treatment but does not have any treatment in it. It is sometimes used to compare against the actual investigational treatment to evaluate effectiveness.

UDCA: ursodeoxycholic acid.

References

1. Livdelzi Gilead Sciences Inc. LIVDELZI® (seladelpar) capsules, for oral use. US Prescribing Information. Foster City, CA Revised August. 2024.
2. Hirschfield GM, Bowlus CL, Mayo MJ, et al. A Phase 3 Trial of Seladelpar in Primary Biliary Cholangitis. N Engl J Med. 2024;390(9):783-794.
3. Gilead Sciences Inc. Data on File.

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 doctor.

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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