

CONSIDERING LIVDELZI?

LIVDELZI is a new treatment for primary biliary cholangitis (PBC). Here are some things to discuss with your doctor to understand if LIVDELZI could be right for you.

1 For people with PBC, LIVDELZI may change what treatment can be: It is the first and only treatment shown to significantly reduce alkaline phosphatase (ALP) and PBC-related itch.

In a clinical study, LIVDELZI improved measures of PBC.*

In participants taking LIVDELZI, about 6 out of 10 met the key study goal for PBC treatment by 12 months.[†] The key study goal was:

- ALP less than 1.67 x the upper limit of normal (ULN)[‡]
- ALP decreased by at least 15% from start of study
- Maintained normal bilirubin levels

LIVDELZI is the only PBC treatment that normalized ALP in 1 out of 4 participants by 12 months.

LIVDELZI is the only PBC treatment proven to significantly reduce itch by 6 months. In the clinical study, LIVDELZI:

- Showed rapid itch reduction as early as month 1
- Reduced PBC itch by ~2x more than the placebo group (a mean change of -3.2 points on the Numerical Rating Scale [NRS][§] by 6 months with LIVDELZI vs -1.7 points in the placebo group)[¶]

Questions to ask your doctor:

- Could LIVDELZI be used to help lower my ALP?
- Can LIVDELZI help reduce my PBC itch?

*In this clinical study of 193 people with PBC, LIVDELZI was given either with urso or alone. The results were compared with the placebo group, which included participants who took placebo (a treatment that does not contain medicine) with or without urso. In this study, 128 participants took LIVDELZI and 65 participants were in the placebo group.

[†]In the clinical study, 2 out of 10 participants in the placebo group met the key study goal for PBC treatment compared to about 6 out of 10 participants taking LIVDELZI.

[‡]ULN refers to the high end of the normal range of a lab results value.

[§]The NRS is a scale of 0-10 that measures itch severity, with 10 being the worst possible itch.

[¶]Participants evaluated in the study began the trial with NRS scores of ≥ 4 .

What is LIVDELZI?

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 patients 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.

What are the possible side effects of LIVDELZI?

LIVDELZI can cause serious side effects, including:

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

Please see Important Safety Information throughout and [Important Facts](#) about LIVDELZI.



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LIVDELZI has an established safety profile across a broad range of people with PBC.

The safety of LIVDELZI was studied in people with PBC in combination with or without UDCA. After the study was over, 96% of participants agreed to enter LIVDELZI's ongoing safety study.

The most common side effects in the LIVDELZI clinical trial were:

- Headache
- Stomach pain
- Nausea
- Abdominal swelling
- Dizziness

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all the possible side effects of LIVDELZI. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Questions to ask your doctor:

- Will any of my other health conditions affect whether LIVDELZI is right for me?
- I am currently taking these medications: (provide a list of current medications to your provider/doctor). Can I take LIVDELZI with the other medications I'm taking?
- I have compensated (stable) cirrhosis. Is LIVDELZI still a potential option for me?

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LIVDELZI is taken as a once-daily pill.

LIVDELZI is prescribed as a 10-mg pill to take once a day, in combination with a dose of UDCA. If you are unable to tolerate UDCA, your doctor may prescribe LIVDELZI alone.

Questions to ask your doctor:

- If I start LIVDELZI, will I continue my current dose of urso?
- Are there any food restrictions I should be aware of while taking LIVDELZI?



Image not to scale.

What are the possible side effects of LIVDELZI? CONT

LIVDELZI can cause serious side effects, including:

- **Changes in liver tests.** Increased liver enzymes in the blood have happened when taking more LIVDELZI than prescribed. Your healthcare provider will do tests to check your liver before you start and during treatment with LIVDELZI.

Tell your healthcare provider right away if you have any of the following signs or symptoms of worsening liver problems during treatment with LIVDELZI:

- swelling of your stomach area (abdomen) from a build-up of fluid
- yellowing of your skin or the whites of your eyes
- pain on the right side of your stomach (abdomen)
- black, tarry, or bloody stools
- coughing up or vomiting blood, or your vomit looks like "coffee grounds"
- mental changes such as confusion, being sleepier than usual or harder to wake up, slurred speech, mood swings, or changes in personality

The most common side effects of LIVDELZI include headache, stomach (abdominal) pain, nausea, abdominal swelling (distension), and dizziness.

Tell your healthcare provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of LIVDELZI.

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Taking notes before and during your doctor's appointment may be helpful. Use this workspace to do so:

My recent PBC symptoms:

Peak Pruritus Numerical Rating Scale (NRS)—can be used to measure PBC-related itch:

No itch	○	○	○	○	○	○	○	○	○	○	○	Worst itch
	1	2	3	4	5	6	7	8	9	10		

My other medications: (provide a list of current medications to your doctor)

Notes:

IF YOU NEED MORE FROM YOUR PBC TREATMENT, ASK IF LIVDELZI COULD WORK FOR YOU.

What should I tell my healthcare provider before taking LIVDELZI?

Tell your healthcare provider about all of your medical conditions, including if you:

- have advanced liver disease.
- think you may have a blockage of the bile ducts in your liver (biliary obstruction).
- are pregnant or plan to become pregnant. It is not known if LIVDELZI will harm your unborn baby.
 - **Pregnancy safety study.** If you become pregnant while taking LIVDELZI, tell your healthcare provider right away. There is a pregnancy safety study for women who take LIVDELZI during pregnancy. Talk to your healthcare provider about providing information to the LIVDELZI pregnancy safety study. The purpose of this pregnancy safety study is to capture information about your health and your baby's health. You or your healthcare provider can report your pregnancy by calling 1-800-445-3235.
- 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 if you take LIVDELZI.

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 certain medicines work. Certain other medicines may affect the way LIVDELZI works.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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