

# How to talk to your healthcare provider about your PBC treatment plan

It's important to feel empowered to share your concerns and goals for your treatment. This guide is designed to help you have a more informed discussion with your healthcare provider. To help with discussions, answer the questions on the following pages and share the completed guide with your healthcare provider at your next appointment.

Name: \_\_\_\_\_ Age: \_\_\_\_\_ Year diagnosed with PBC: \_\_\_\_\_

## Your goals and current treatment plan

### Your PBC treatment goals

- ☐ I want to improve my PBC lab results
- ☐ I want to achieve a normal alkaline phosphatase (ALP) level
- ☐ I want to improve my PBC symptoms (such as itch)
- ☐ I want to lower my risk of PBC progression

Other: \_\_\_\_\_

### List all the medications you currently take

For PBC: \_\_\_\_\_

\_\_\_\_\_

List any concerns about your current PBC treatment:

\_\_\_\_\_

\_\_\_\_\_

Other medications: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

### Your current PBC lab levels (such as ALP)

\_\_\_\_\_ Date: \_\_\_\_\_

\_\_\_\_\_ Date: \_\_\_\_\_

Is your ALP level within the normal range?

- ☐ Yes ☐ No ☐ I'm not sure

**Note:** It is important to talk to your healthcare provider about all of your health concerns.

## PBC-related itch and impact

### Did you know up to 70% of people living with PBC experience itch?

Itch can disrupt sleep for some people with PBC, which may contribute to daytime sleepiness and fatigue.

### Itch or itch-like sensations

Do you experience itch or itch-like sensations?

- ☐ Yes ☐ No

How often do you experience itch?

- ☐ Never ☐ Infrequently ☐ Monthly ☐ Weekly ☐ Daily

Treatments or strategies you've tried or are currently using to manage PBC itch:

\_\_\_\_\_

### Your concerns about itch

- ☐ Scratching that causes pain or discomfort
- ☐ Disrupts my sleep and makes me feel tired
- ☐ Affects my performance at work
- ☐ Causes me to miss social events
- ☐ Makes me feel embarrassed
- ☐ Causes emotional burden

Other: \_\_\_\_\_

### Your other concerns

- ☐ I have additional concerns (other than itch)

Explain: \_\_\_\_\_

\_\_\_\_\_

Asking questions and discussing any symptoms or health concerns you may have can help you have a meaningful conversation with your healthcare provider about your treatment.

## 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.



## LIVDELZI is the only treatment for adults with PBC to significantly improve key PBC lab results and itch

### In the clinical trial, LIVDELZI:



#### Improved key PBC lab results

in significantly more people compared with placebo at 1 year



#### Lowered ALP to normal

at 1 year, in significantly more people compared with placebo



#### Reduced itch

starting at 1 month, with significant improvement seen at 6 months

### Trial design

In a clinical trial of 193 people with PBC, 128 people took LIVDELZI with or without ursodeoxycholic acid (ursodiol). The results were compared with 65 people who took placebo (a treatment that does not contain medicine) with or without ursodiol.

### Trial data



**PBC lab results:** The main trial goal was to improve key PBC lab results by achieving ALP levels of less than 1.67 times the upper limit of normal (ULN), achieving ALP decreases of at least 15% from the start of the trial, and maintaining normal bilirubin levels at 1 year. 62% of people taking LIVDELZI met the main trial goal for PBC treatment compared with 20% of people taking placebo.



**ALP:** A secondary trial goal was to measure ALP normalization at 1 year. LIVDELZI lowered ALP to normal in 25% of people compared with 0% of people taking placebo.



**Itch:** Another secondary trial goal was to measure itch reduction in people with Numerical Rating Scale (NRS) scores of 4 or higher at 6 months. The average NRS score at the start of the trial was 6.1 for LIVDELZI (49 people) and 6.6 for placebo (23 people). The NRS is a scale from 0 to 10 that measures itch severity, with 0 being no itch and 10 being the worst possible itch. LIVDELZI reduced NRS scores by an average of 3.2 vs 1.7 for placebo at 6 months.

The most common side effects for LIVDELZI in the clinical trial include headache, stomach (abdominal) pain, nausea, abdominal swelling (distension), and dizziness.

### Good questions to ask your healthcare team about LIVDELZI

- Can LIVDELZI help my PBC?
- Can LIVDELZI be used to help lower or normalize my ALP?
- How might LIVDELZI help reduce my itch?
- Can you explain to me more about the LIVDELZI safety profile?
- What are the possible side effects of LIVDELZI?
- Can I take LIVDELZI with the other medications I'm taking?

#### Other questions you have:

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## IMPORTANT SAFETY INFORMATION

### 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 additional Important Safety Information throughout and Important Facts about LIVDELZI on the last page.



Scan the code  
to learn more at  
LIVDELZI.com

For adults with primary biliary cholangitis (PBC)

Let **LIVDELZI**  
take on your PBC  
while you take in the moment

Actor portrayals.

## IMPORTANT SAFETY INFORMATION (cont'd)

### What are the possible side effects of LIVDELZI? (cont'd)

**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.

**Please see Important Facts about LIVDELZI on the next page.**

### 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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

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## ABOUT LIVDELZI

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## IMPORTANT FACTS

This is only a brief summary of important information about LIVDELZI and does not replace talking to your healthcare provider about your condition and your treatment.

## 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.
- **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:

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**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.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

## HOW TO TAKE LIVDELZI

Take LIVDELZI by mouth 1 time each day with or without food.

## GET MORE INFORMATION

- This is only a brief summary of important information about LIVDELZI. Talk to your healthcare provider or pharmacist to learn more.
- Go to LIVDELZI.com, or call 1-800-GILEAD-5.