

# Lower is better with Livdelzi

For people with primary biliary cholangitis (PBC), LIVDELZI is the first and only treatment shown to significantly reduce alkaline phosphatase (ALP) and PBC-related itch vs placebo.\*

## 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.<sup>†</sup> The key study goal was:
  - ALP less than 1.67 x the upper limit of normal (ULN)<sup>‡</sup>
  - 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 in the placebo group (a mean change of -3.2 points on the Numerical Rating Scale [NRS]<sup>§</sup> by 6 months with LIVDELZI vs -1.7 points in the placebo group)

\*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.

<sup>†</sup>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.

<sup>‡</sup>ULN refers to the high end of the normal range of a lab results value.

<sup>§</sup>The NRS is a scale of 0-10 that measures itch severity, with 10 being the worst possible itch.

*Important information if your doctor has determined that LIVDELZI is right for you.*

## 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.

## 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.

 **Livdelzi**<sup>®</sup>  
seladelpar 10mg  
Capsules

## 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 ULN
- ALP decreased by at least 15% from start of study
- Maintained normal bilirubin levels

lower  ALP

In the clinical study, **reduction in ALP** was evaluated as a secondary study goal

Provided **rapid and sustained reduction in ALP** (42% ALP reduction on average by 12 months from start of study, compared to 4% of participants 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.

## IMPORTANT SAFETY INFORMATION, CONT

### 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.

## IN A CLINICAL STUDY, LIVDELZI improved measures of PBC.

In the LIVDELZI clinical study, 193 people with PBC—most of whom were already on urso (UDCA)—continued on urso and were given either LIVDELZI or placebo. Twelve people who could not tolerate urso were given only LIVDELZI or placebo. In this study, 128 participants took LIVDELZI and 65 participants were in the placebo group.



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

## IMPORTANT SAFETY INFORMATION, CONT

### What are the possible side effects of LIVDELZI? CONT

**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

LIVDELZI is the only PBC treatment proven to significantly reduce itch by 6 months.

less **ITCH**

In the clinical study, LIVDELZI:

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

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  $\geq 4$ .

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

## IMPORTANT SAFETY INFORMATION, CONT

### What are the possible side effects of LIVDELZI? CONT

**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 additional Important Safety Information throughout and **Important Facts** about LIVDELZI.

## 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 were:

- headache
- stomach pain
- nausea
- abdominal swelling
- dizziness

You should tell your healthcare provider if you have any side effects that bother you or do not go away.

To learn more about LIVDELZI, visit [LIVDELZI.com](https://www.livdelzi.com)

## IMPORTANT SAFETY INFORMATION, CONT

### 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).

## TAKING THE NEXT STEP on your PBC treatment journey.

### How to take LIVDELZI.



Since the recommended dose of LIVDELZI is one 10-mg capsule, taken orally once daily, LIVDELZI can fit into your schedule.

### Take LIVDELZI exactly as your doctor tells you to.

- Take LIVDELZI with or without food
- Do not take more LIVDELZI than your healthcare provider tells you to
- If you take too much LIVDELZI, call your healthcare provider or get emergency medical help right away

### IMPORTANT SAFETY INFORMATION, CONT

#### What should I tell my healthcare provider before taking LIVDELZI? CONT

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

- 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.

## Getting started.

LIVDELZI is available through specialty pharmacies, which can deliver LIVDELZI directly to you.

You should also know about the **Gilead Support Path Program**, which offers information and resources to help people prescribed LIVDELZI understand their coverage and financial options.

## Once you've been prescribed LIVDELZI, you can get enrolled in 4 easy steps:

### Step 1

Fill out the Support Path PBC enrollment form

### Step 2

A program specialist will call you to confirm your program enrollment

### Step 3

Connect with a program specialist to find out if your treatment is covered by your health insurance plan

### Step 4

A program specialist will conduct a benefits investigation and identify potential financial support options

## IMPORTANT SAFETY INFORMATION, CONT

### What should I tell my healthcare provider before taking LIVDELZI? CONT

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

- 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.





For adults with **primary biliary cholangitis (PBC)**



If you need help affording your prescribed Gilead treatment, the Support Path Co-pay Coupon Program may be able to help eligible patients.

To enroll in the Support Path Program or ask about the Co-pay Coupon Program, you can connect live with a Support Path Program specialist at [MySupportPath.com](https://www.mysupportpath.com) or at **1-855-7-MYPATH (1-855-769-7284)** Monday-Friday, 9 AM to 8 PM ET.

## IMPORTANT SAFETY INFORMATION, CONT

### What should I tell my healthcare provider before taking LIVDELZI? CONT

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

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



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