



For adults with primary biliary cholangitis (PBC)

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

Actor portrayals.

## 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 Important Safety Information throughout and [Important Facts](#) about LIVDELZI on the last page.

# PBC (short for primary biliary cholangitis) is a rare autoimmune disease of the liver



PBC causes **inflammation** in the bile ducts of the liver.



Over time, **scarring** from this inflammation can block the bile ducts, leading to liver damage and reduced liver function.



If left untreated or not treated well enough, PBC can lead to end-stage liver disease and the need for a **liver transplant**.

## What causes PBC?

The exact cause of PBC is unknown and it is thought that genetic and environmental factors play a role. Researchers have ruled out alcohol as a possible cause.

## Measuring PBC progression

Your healthcare provider may monitor a few things to see if your PBC is under control or progressing, including:

### ALP

An enzyme also known as **alkaline phosphatase** or "**alk phos**"

### Scarring

FibroScans are used to measure the amount of scarring in your liver

## PBC symptoms

When the liver doesn't function properly due to PBC, it can lead to symptoms that you may not realize are caused by liver disease. Some of the most common PBC symptoms include:



**FATIGUE**



**ITCHY SKIN**

**Research has shown that elevated ALP levels are associated with liver damage that may ultimately require a liver transplant**

**Up to 70% of people with PBC experience itch**

For some people, itch can even interrupt sleep, which may contribute to daytime sleepiness and fatigue

# Treating PBC

When treating PBC, your healthcare team will aim to improve key PBC lab results, including ALP. Getting your ALP to a lower level has been shown to reduce the risk of PBC progression.

## PBC treatment goals



Lower your ALP



Lower the risk of disease progression. Disease progression may include:

- Liver scarring (fibrosis)
- Irreversible liver damage (cirrhosis)
- Liver failure and transplant



Reduce the symptoms caused by PBC



## First-line PBC treatment

The current primary treatment for people living with PBC is ursodiol (also known as urso or UDCA). **But about 40% of people with PBC continue having high ALP levels despite taking ursodiol.**

## Expanding treatment options

For the first time since 2016, there are additional treatment options available for people with PBC.

**If you still have elevated ALP levels despite treatment, talk to your healthcare team—you may need to try another PBC treatment**

# How LIVDELZI is designed to work

**LIVDELZI is designed to work differently from other PBC treatments. It targets a specific cell receptor in the liver called PPAR-delta. Activation of PPAR-delta is known to help reduce the production of bile acids**

In addition to helping control bile acid creation, it's also believed that activation of PPAR-delta affects parts of certain liver cells that are involved in inflammation and liver scarring.

But the way LIVDELZI works to treat PBC is not fully understood.

PPAR-delta=peroxisome proliferator-activated receptor delta.



## IMPORTANT SAFETY INFORMATION (cont'd)

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

**LIVDELZI can cause serious side effects, including: (cont'd)**

- **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

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



Let **LIVDELZI**  
help improve key  
PBC lab results

## LIVDELZI improved key PBC lab results

**Significantly more** people who took LIVDELZI (62%) saw all 3 key PBC lab results improve at 1 year compared with people who took placebo (20%)



About 6 in 10 people

### LIVDELZI was studied in a 12-month clinical trial in 193 people with PBC

- 128 people took LIVDELZI with or without ursodiol
- 65 people took a placebo (a treatment that does not contain medicine) with or without ursodiol

Comparing results from people taking LIVDELZI with those taking placebo, the main goal of the clinical trial was to see if LIVDELZI helped people improve 3 key PBC lab results:

- ALP levels less than 1.67 x the upper limit of normal (ULN)
- A decrease in ALP levels of at least 15% from start of trial
- Normal bilirubin levels

Other goals of the clinical trial were to determine if LIVDELZI could help:

- Lower ALP levels over 12 months
- Achieve normal ALP levels (ALP less than or equal to ULN)
- Reduce itch in people with Numerical Rating Scale (NRS) scores of 4 or higher at 6 months

Actor portrayals.

### IMPORTANT SAFETY INFORMATION (cont'd)

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

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

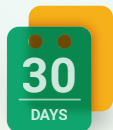
Tell your healthcare provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of LIVDELZI.

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

 **Livdelzi**  
seladelpar 10mg  
Capsules

Let **LIVDELZI**  
help lower your ALP

# LIVDELZI lowered ALP levels at 1 month and kept them lower at the 1-year mark



36% average  
**ALP reduction at 30 days**  
(vs 5% for placebo)



People taking LIVDELZI experienced  
**42% average ALP reduction at 1 year**  
(vs 4% for placebo)



1 in 4 people (25%) taking LIVDELZI reached  
**normal ALP levels at 1 year**  
(vs none for placebo)



Actor portrayals.

## IMPORTANT SAFETY INFORMATION (cont'd)

### 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).

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

 **Livdelzi**  
seladelpar 10mg  
Capsules



Let **LIVDELZI**  
help improve your itch

# Itch improvement at 1 month, with significant improvement at 6 months— a first in PBC

People who began the trial with NRS scores  $\geq 4$  saw:



## Rapid itch improvement

LIVDELZI  
started improving itch  
at 30 days



## Significant itch improvement

At 6 months, people taking LIVDELZI  
experienced an average itch reduction from  
the start of the trial of about 52% vs 26%  
for those taking placebo (3.2-point decrease  
on the NRS vs 1.7-point decrease for placebo)

The NRS is a scale of 0 to 10 that measures itch severity, with 0 being no itch and 10 being the worst possible itch. People evaluated in the trial who already had itch began the trial with NRS scores of  $\geq 4$ ; the average NRS score at the start of the trial was 6.1 for LIVDELZI (49 people) and 6.6 for placebo (23 people).

## IMPORTANT SAFETY INFORMATION (cont'd)

### What should I tell my healthcare provider before taking LIVDELZI? (cont'd)

Tell your healthcare provider about all of your medical conditions, including if you: (cont'd)

- 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.

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

 **Livdelzi**  
seladelpar 10mg  
Capsules

# LIVDELZI has an established safety profile

## The most common side effects in the clinical trial\*

Side effect	LIVDELZI (128 people)	Placebo (65 people)
Headache	8% (10 people)	3% (2 people)
Stomach pain	7% (9 people)	2% (1 person)
Nausea	6% (8 people)	5% (3 people)
Stomach bloating	6% (8 people)	3% (2 people)
Dizziness	5% (6 people)	2% (1 person)

\*Side effects reported in 5% or more of people in clinical trials taking LIVDELZI with or without ursodiol or placebo with or without ursodiol.

Actor portrayals.

**People taking LIVDELZI had a lower discontinuation rate (3.1%) due to side effects vs placebo (4.6%)**

## IMPORTANT SAFETY INFORMATION (cont'd)

### What should I tell my healthcare provider before taking LIVDELZI? (cont'd)

Tell your healthcare provider about all of your medical conditions, including if you: (cont'd)

- 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.

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

 **Livdelzi**  
seladelpar 10mg  
Capsules



# With once-daily dosing, LIVDELZI can fit into your routine



Once-daily  
capsule



Can be taken with or  
without food



Can be taken any  
time of day

## Take LIVDELZI exactly as your healthcare provider prescribes

- Follow your healthcare provider's instructions with regard to taking LIVDELZI with ursodiol, on its own, and/or with other medications you may be taking
- 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



Actor portrayals.

## IMPORTANT SAFETY INFORMATION (cont'd)

### What should I tell my healthcare provider before taking LIVDELZI? (cont'd)

**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.

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

 **Livdelzi**  
seladelpar 10mg  
Capsules



# Financial resources

## We're here to help you

The **Gilead Support Path® Program** 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:



Fill out the Support Path enrollment form



A program specialist will call you to confirm your program enrollment



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



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



**\$0**  
**CO-PAY\***

You may pay as low as a **\$0 co-pay\***  
**with the LIVDELZI Co-pay  
Coupon Program**

\*Co-pay coupon support is available for commercially insured eligible patients only. Additional restrictions may apply. Subject to change; for full terms and conditions, visit [www.mysupportpath.com/co-pay](http://www.mysupportpath.com/co-pay). This is not health insurance. Only accepted at participating pharmacies.





Actor portrayals.

**If you need help affording LIVDELZI, the LIVDELZI Co-pay Coupon Program may be able to help\***



To enroll in the **Support Path Program** or **ask about the LIVDELZI Co-pay Coupon Program**, you can connect live with a Support Path program specialist at **1-855-7-MYPATH** (1-855-769-7284)

Monday-Friday, 9 AM to 8 PM ET

\*Co-pay coupon support is available for commercially insured eligible patients only. Additional restrictions may apply. Subject to change; for full terms and conditions, visit [www.mysupportpath.com/co-pay](http://www.mysupportpath.com/co-pay). This is not health insurance. Only accepted at participating pharmacies.



Scan the code to learn more at [LIVDELZI.com](http://LIVDELZI.com)

 **Livdelzi**  
seladelpar 10mg  
Capsules

For adults with primary biliary cholangitis (PBC)

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

**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 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 NRS scores of 4 or higher at 6 months. 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.

## 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.
- **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.

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

**Ask your  
healthcare provider  
about LIVDELZI**



LIVDELZI, the LIVDELZI Logo, SUPPORT PATH, the SUPPORT PATH Logo, GILEAD, and the GILEAD Logo are trademarks of Gilead Sciences, Inc., or its related companies.  
© 2025 Gilead Sciences, Inc. All rights reserved. US-LIVC-0059 03/25





(liv del' zee)

## ABOUT 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.

## 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.

## 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:

- 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.

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.