

PATIENT INFORMATION
LIVDELZI (liv del' zee)
(seladelpar)
capsules, for oral use

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.

Before taking LIVDELZI, tell your healthcare provider about all 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.

How should I take LIVDELZI?

- Take LIVDELZI exactly as your healthcare provider 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 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.
- If you take too much LIVDELZI, call your healthcare provider or get emergency medical help right away.

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.

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)
- 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 should I store LIVDELZI?

- Store LIVDELZI at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep LIVDELZI and all medicines out of the reach of children.**

General information about the safe and effective use of LIVDELZI.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use LIVDELZI for a condition for which it was not prescribed. Do not give LIVDELZI to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about LIVDELZI that is written for health professionals.

What are the ingredients in LIVDELZI?

Active ingredient: seladelpar lysine

Inactive ingredients: butylated hydroxytoluene, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, mannitol, microcrystalline cellulose, and hard gelatin shells.

The light gray opaque (body) and dark blue opaque (cap) capsule shells contain gelatin, titanium dioxide, black iron oxide, yellow iron oxide, red iron oxide and the colorant FD&C Blue #2.

Distributed by: Gilead Sciences, Inc., Foster City, CA 94404.

LIVDELZI is a trademark of Gilead Sciences, Inc., or its related companies.

© 2024 Gilead Sciences, Inc. All rights reserved. 217899-GS-000

For more information, call 1-800-445-3235 or go to www.LIVDELZI.com.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Approved: 08/2024