Patient leaflet in accordance with the Pharmacists' (Products) Regulations - 1986
This medicine is to be supplied by doctor's prescription only

Livdelzi®
Seladelpar 10 mg
hard capsules

Active ingredients:

Each hard capsule contains seladelpar lysine dihydrate equivalent to 10 mg seladelpar.

Inactive and allergenic substances: see section 6 "Additional information".

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. This leaflet contains essential information about this medicine. If you have any further questions, ask your doctor or pharmacist. Keep this leaflet. You may need to read it again. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if it seems that their medical condition is similar to yours. If you experience any side effects, talk to your doctor or pharmacist, even if you experience any side effects that are not listed in this leaflet (see section 4).

1. What is the medicine intended for?

Livdelzi is indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA alone, or as monotherapy in those unable to tolerate UDCA.

Therapeutic group:

Bile and liver therapy, other drugs for bile therapy.

How Livdelzi works

The active substance in Livdelzi, seladelpar, works by activating the PPAR delta receptor. This protein regulates levels of bile acids, inflammation, and fibrosis (formation of scar tissue). This reduces the production and the build-up of bile in the liver and also reduces inflammation of the liver.

2. Before using the medicine

Do not take this medicine if:

- if you are allergic to the active ingredient (seladelpar) or any of the other ingredients of this medicine (listed in section 6).

  → If this applies to you, **do not take Livdelzi and tell your doctor immediately.**

Special warnings relating to the use of this medicine

Your doctor may do blood tests before you start Livdelzi and during treatment to check how well your liver is working (liver function). Your doctor may need to pause your treatment if these tests show that

your liver function worsens. They may then start it again if your liver recovers. If your liver function worsens again after restarting treatment your doctor may permanently stop treatment with Livdelzi.

Contact your doctor immediately if you develop symptoms of liver dysfunction (inflammation of the liver) or complete biliary obstruction (blocked bile duct) during treatment including:
- belly (abdominal) pain
- jaundice (yellowing of the skin and the whites of the eyes)
- dark urine
- light coloured stools

Children and adolescents

Livdelzi is intended for use by adults aged 18 and older. Livdelzi is not intended for use by children and adolescents below 18 years of age.

Drug-Drug Interactions

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including non-prescribing medicines and food supplements.

In particular, tell your doctor, pharmacist or nurse if you are taking medicines called:

- Probenecid, used to treat gout
- Cyclosporine, used to prevent the body from rejecting a transplanted organ
- 'bile acid binding resins' (such as cholestyramine, colestipol, or colesevelam adsorb) - used to lower blood cholesterol levels. These may make Livdelzi work less well if taken too close to when you take Livdelzi.
- If you are taking a 'bile acid binding resin', you will need to take Livdelzi at least 4 hours before or at least 4 hours after taking a 'bile acid binding resin'. See section 3 for more information.

The following medicines may increase the risk of side effects with Livdelzi by increasing the amount of Livdelzi in the blood:

- Fluconazole, used to treat fungal infections
- Mifepristone, used for the medical termination of a pregnancy

Taking the medicine and food

You can take this medicine with or without food.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
There are no or limited amount of data from the use of seladelpar in pregnant women. As a precautionary measure, it is preferable to avoid the use of seladelpar during pregnancy.

It is unknown whether seladelpar or its metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from seladelpar therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Driving and using machines
Seladelpar has no or negligible influence on the ability to drive, cycle or use tools or machines.

Important information about some ingredients of the medicine

Livdelzi contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per hard capsule, that is to say essentially 'sodium-free'.

3. How to take the medicine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure regarding the dose and treatment regimen of the product.

The dose and treatment regimen will be determined by a doctor only.

The recommended dose is one 10 mg capsule taken once daily.

Do not exceed the recommended dose.

How to take

- Swallow the capsule whole, with water. There is no information regarding opening and dispersing the contents of the capsule.
- You can take this medicine with or without food.
- Livdelzi is taken either together with another medicine called 'ursodeoxycholic acid' (UDCA, also called urso or ursodiol) – or by itself if you cannot take UDCA.

If you are already taking a bile acid binding resin:

- Take Livdelzi at least 4 hours before or at least 4 hours after-taking the bile acid binding resin.
- If you are unsure, ask your doctor, pharmacist or nurse.

If you take more Livdelzi than you should

If you take more Livdelzi than you should, tell your doctor, pharmacist or nurse straight away. Symptoms of overdose may include dark urine or muscle pain. If you take more than you should or if a child has accidentally swallowed some of the medicine, contact your doctor or nearest hospital emergency department immediately and bring the medicine carton with you.

If you forget to take Livdelzi

If you forget to take Livdelzi, skip the missed dose and take the next dose when it is due. Do not take a double dose to make up for the one that you missed.

If you stop taking Livdelzi

It is important that you take your treatment as your doctor has ordered. Even if your health improves, do not stop taking this medicine unless your doctor tells you to. Do not stop taking this medicine without talking to your doctor, pharmacist or nurse. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Side Effects

Like all medicines, this medicine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Very common: may effect more than 1 in 10 users

- belly (abdominal) pain

Common: may affect up to 1 in 10 users

- headache
- feeling sick (nausea)
- swelling of the belly (abdominal distension)

→ **If a side effect has appeared, if any of the side effects worsen or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.**

Reporting of side effects
You can report any side effects to the Ministry of Health by clicking on the link "Report side effects due to medical treatment" that is located on the Ministry of Health homepage (www.health.gov.il) which redirects to the online form for reporting side effects or by clicking on the link: https://sideeffects.health.gov.il.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store the medicine

Prevent poisoning! Keep this medicine out of the sight and reach of children and/or babies. In this way you will prevent poisoning. Do not induce vomiting without a doctor's express instruction.

Do not use this medicine after the expiry date which is stated on the package after "EXP". The expiry date refers to the last day of that month.

Store below 25°C until end of shelf life.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away you no longer use. These measures will help protect the environment.

6. Additional information

What Livdelzi contains

In addition to the active ingredient, the medicine also contains:

- capsule content – mannitol (Pearlitol 200 SD), microcrystalline cellulose (Avicel PH 302, Avicel PH 101), croscarmellose sodium (Ac-di-sol), magnesium stearate (Hyqual, vegetable source), colloidal silicon dioxide (Cab-O-Sil M5P), butylated hydroxytoluene
- capsule shell – gelatin, titanium dioxide, black iron oxide (E172), red iron oxide (E172), yellow iron oxide (E172), FD&C Blue #2

- black ink used to imprint “10” on the body of the capsule shell – shellac (E904), propylene glycol (E1520), purified water, potassium hydroxide (E525), black iron oxide irradiated (E172)
- white ink used to imprint “CBAY” on the cap of the capsule – shellac (E904), propylene glycol (E1520), sodium hydroxide (E524), povidone (E1201), titanium dioxide (E171)

What Livdelzi looks like and contents of the pack

This medicine is a hard capsule with a dark blue opaque cap and a light grey opaque body, printed with “CBAY” in white ink on the cap and “10” in black ink on the body. The capsules are packaged in a bottle with a child resistant cap.

Each bottle contains 30 capsules.

Manufacturer
Gilead Sciences Ireland UC
IDA Business and Technology Park
Carrigtohill
Co. Cork
Ireland

Registration Holder
Gilead Sciences Israel Ltd.
4 HaHarash Street
Hod Hasharon 4524075
Israel

The medicine’s registration no. in the national register of medicines at the Ministry of Health: 38423

For simplicity and ease of reading, this leaflet was phrased in the masculine. Nevertheless, this medicine is intended for both sexes.

This leaflet format has been determined by the Ministry of Health and the content has been checked and approved in December 2025.

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