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Lyvdelzi[1] (*seladelpar*)

An overview of Lyvdelzi and why it is authorised in the EU

What is Lyvdelzi and what is it used for?

Lyvdelzi is a medicine used to treat adults with a liver disease known as primary biliary cholangitis.

Primary biliary cholangitis is an autoimmune condition in which there is gradual destruction of the bile ducts in the liver. These ducts transport a fluid called bile from the liver to the intestines, where it is used to help digest fats. As a result of the damage to the ducts, bile builds up in the liver, causing damage to liver tissue. This may lead to scarring and liver failure and may increase the risk of liver cancer.

Lyvdelzi is used together with another medicine, ursodeoxycholic acid (UDCA), in patients for whom UDCA alone does not work well enough, and on its own in patients who cannot take UDCA.

Primary biliary cholangitis is rare, and Lyvdelzi was designated an 'orphan medicine' (a medicine used in rare diseases) on 16 October 2017. Further information on the orphan designation can be found on the EMA website.

Lyvdelzi contains the active substance seladelpar.

How is Lyvdelzi used?

Lyvdelzi can only be obtained with a prescription and is available as capsules to be taken by mouth.

For more information about using Lyvdelzi, see the package leaflet or contact your doctor or pharmacist.

How does Lyvdelzi work?

The active substance in Lyvdelzi, seladelpar, works by attaching to and activating a protein called PPAR delta, which is thought to be involved in controlling the production of bile acid. By activating PPAR delta, Lyvdelzi reduces the production of bile acid in the liver, which in turn is expected to reduce liver inflammation and scarring in people with primary biliary cholangitis.

[1] Previously known as Seladelpar Gilead

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What benefits of Lyvdelzi have been shown in studies?

In a main study involving 193 adults with primary biliary cholangitis, Lyvdelzi was compared with placebo (a dummy treatment). The majority of patients had been taking UDCA and continued taking it during the study. The main measure of effectiveness was based on the number of patients whose blood levels of the substances alkaline phosphatase (ALP) and bilirubin (markers of liver damage) decreased to a level considered normal (for both ALP and bilirubin) and by at least 15% (for ALP) after 1 year of treatment.

The study showed that Lyvdelzi was more effective than placebo at reducing the blood levels of ALP and bilirubin. Overall, levels decreased by the required amount in around 62% (79 out of 128) of patients treated with Lyvdelzi, compared with around 20% (13 out of 65) of patients on placebo. Additionally, Lyvdelzi also improved cholestasis pruritus (itching) compared with placebo.

What are the risks associated with Lyvdelzi?

For the full list of side effects and restrictions with Lyvdelzi, see the package leaflet.

The most common side effect with Lyvdelzi (which may affect more than 1 in 10 people) is abdominal (belly) pain. Other common side effects (which may affect up to 1 in 10 people) include headache, nausea and abdominal distension (swelling).

Why is Lyvdelzi authorised in the EU?

At the time of authorisation, there was a need for new primary biliary cholangitis treatments for patients for whom UDCA alone does not work well enough or who cannot take UDCA.

Lyvdelzi was shown to be effective at reducing markers of liver damage in these patients. The medicine was also shown to improve cholestatic pruritus (itching), a bothersome symptom of primary biliary cholangitis. However, there was a lack of data on the long-term improvements in patients' liver function.

Regarding safety, the side effects of Lyvdelzi in the studies were mostly mild and manageable. The European Medicines Agency therefore decided that Lyvdelzi's benefits are greater than its risks and it can be authorised for use in the EU.

Lyvdelzi has been given conditional authorisation. This means that it has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need. The European Medicines Agency considers that the benefit of having the medicine available earlier outweighs any risks associated with using it while awaiting further evidence.

The company must provide further data on Lyvdelzi. It must submit results from a study evaluating the long-term effectiveness and safety of Lyvdelzi in patients with primary biliary cholangitis. Every year, the Agency will review any new information that becomes available.

What measures are being taken to ensure the safe and effective use of Lyvdelzi?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Lyvdelzi have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Lyvdelzi are continuously monitored. Suspected side effects reported with Lyvdelzi are carefully evaluated and any necessary action taken to protect patients.

Other information about Lyvdelzi

Seladelpar Gilead received a conditional marketing authorisation valid throughout the EU on 20 February 2025.

The name of the medicine was changed to Lyvdelzi on 14 April 2025.

Further information on Lyvdelzi can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/lyvdelzi.

This overview was last updated in 06-2025.