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Seladelpar Gilead (*seladelpar*)

An overview of Seladelpar Gilead and why it is authorised in the EU

What is Seladelpar Gilead and what is it used for?

Seladelpar Gilead 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.

Seladelpar Gilead 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 Seladelpar Gilead 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.

Seladelpar Gilead contains the active substance seladelpar.

How is Seladelpar Gilead used?

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

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

How does Seladelpar Gilead work?

The active substance in Seladelpar Gilead, 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, Seladelpar Gilead 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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What benefits of Seladelpar Gilead have been shown in studies?

In a main study involving 193 adults with primary biliary cholangitis, Seladelpar Gilead 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 Seladelpar Gilead 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 Seladelpar Gilead, compared with around 20% (13 out of 65) of patients on placebo. Additionally, Seladelpar Gilead also improved cholestasis pruritus (itching) compared with placebo.

What are the risks associated with Seladelpar Gilead?

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

The most common side effect with Seladelpar Gilead (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 Seladelpar Gilead 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.

Seladelpar Gilead 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 Seladelpar Gilead in the studies were mostly mild and manageable. The European Medicines Agency therefore decided that Seladelpar Gilead's benefits are greater than its risks and it can be authorised for use in the EU.

Seladelpar Gilead 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 Seladelpar Gilead. It must submit results from a study evaluating the long-term effectiveness and safety of Seladelpar Gilead 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 Seladelpar Gilead?

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

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

Other information about Seladelpar Gilead

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

Further information on Seladelpar Gilead can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/seladelpar-Gilead.

This overview was last updated in 01-2025.