swissmedic

Summary report on authorisation dated 30 March 2026

Lyvdelzi® (active substance: seladelpar)

Temporary authorisation in Switzerland: 9 December 2025

Hard capsules as monotherapy or in combination with ursodeoxycholic acid (UDCA) for the treatment of adults with primary biliary cholangitis (PBC) who have an inadequate response to UDCA alone or who are unable to tolerate UDCA

About the medicinal product

Lyvdelzi contains the active substance seladelpar and is used for the treatment of primary biliary cholangitis (PBC). PBC is a rare, chronic liver disease in which the small bile ducts become increasingly damaged over time. As a result, bile is no longer able to drain properly, leading to inflammation and, in the long term, scarring of the liver. Many patients suffer from fatigue, itching or signs of impaired liver function.

Lyvdelzi is intended for adults who have not achieved a sufficient improvement despite treatment with ursodeoxycholic acid (UDCA), the current standard medication, or who are unable to tolerate UDCA.

The disease primarily affects middle-aged women and, if left untreated, can ultimately lead to severe liver damage. Lyvdelzi offers a new treatment option that influences impaired bile flow, potentially reducing the signs and symptoms of the disease.

Mode of action

Lyvdelzi works by affecting certain processes in the liver that are disrupted in PBC. In PBC, bile builds up in the liver because the small bile ducts become increasingly damaged over time. This build-up can irritate and stress the liver tissue.

The active substance seladelpar works by inhibiting bile acid synthesis and altering bile composition, reducing the inflammation of the bile ducts and the stress on the liver.

Administration

Lyvdelzi is a prescription-only medicine. The treatment must be initiated and monitored regularly by a doctor.

Lyvdelzi is administered as a hard capsule to be swallowed. Each capsule contains 10 mg of seladelpar. The recommended dose is

one capsule once daily, taken in the morning with or without food.

Lyvdelzi can be used together with UDCA or on its own if UDCA is not tolerated.

Efficacy

The efficacy of Lyvdelzi was investigated in the controlled study CB8025-32048 with 193 adults who continued to show clear symptoms of PBC despite treatment with UDCA or who were unable to tolerate UDCA. The participants in this trial received either Lyvdelzi or a dummy drug (placebo) and were followed up for periods up to 12 months.

The study showed that Lyvdelzi significantly improved the liver parameters. Over half of the treated patients achieved a combined improvement, including lower liver enzyme levels and stable bilirubin concentrations (a substance that rises when bile flow is obstructed). These improvements occurred significantly more frequently than with placebo. Itching, a symptom of PBC that can often be very stressful, was improved in many participants.

The study demonstrated the efficacy of Lyvdelzi even at an early stage in the treatment, and the improvements persisted throughout the follow-up period. However, further studies are being conducted since no long-term data are available at this point.

Precautions, undesirable effects, & risks

Lyvdelzi must not be used in those who are hypersensitive to the active substance or any of the capsule excipients.

The very common undesirable effects (affecting more than 1 in 10 of those treated) included abdominal pain. Common undesirable effects (less than 1 in 10, but more than 1 in 100 people) are nausea, headache, abdominal distension and anaemia.

Bone fractures were observed in rare cases. Some patients also showed slight changes in kidney parameters.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Limited treatment options are currently available for patients with PBC who are unable to tolerate UDCA or who continue to have elevated liver parameters or stressful symptoms despite treatment with UDCA.

In the clinical trial, Lyvdelzi managed to improve the results of important laboratory tests that indicate how severely the liver is affected by the obstructed bile flow. Symptoms such as itching also improved in many patients. These positive effects occurred more frequently than with a dummy drug.

At the same time, the known risks of the medicinal product were carefully assessed. The most common undesirable effects were usually mild or moderate. More serious undesirable effects were rare, and the treatment can be controlled effectively at the recommended dosage. Since not all the long-term data are currently available, further clinical trials are planned to confirm the long-term benefit in terms of slowing the progression of both the illness and liver damage. Nevertheless, the benefit for the patients affected still outweigh the existing risks.

Based on these findings, Swissmedic has temporarily authorised the medicinal product Lyvdelzi, containing the active substance

seladelpar, in Switzerland for the treatment of PBC in adults.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals: Lyvdelzi®

Information for patients (package leaflet): Information for patients Lyvdelzi®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated in the Public Summary SwissPAR.

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