swissmedic

Summary report on authorisation dated 28 August 2026

Livmarli® (active substance: maralixibat)

Indication extension in Switzerland: 12 May 2026

Oral solution for the treatment of cholestatic pruritus (itching) in patients aged 12 months and older with progressive familial intrahepatic cholestasis (PFIC)

About the medicinal product

Livmarli contains the active substance maralixibat.

The medicinal product Livmarli is used for the treatment of cholestatic pruritus (itching caused by bile build-up) in patients aged 12 months and older with PFIC.

PFIC is a a group of rare hereditary liver diseases in which bile acid formation or transport is disrupted. As a result, bile flow slows or stalls in the body (cholestasis) from early childhood, causing an accumulation of bile acids and other components of bile in the liver and blood. The disease can progress, leading to severe liver damage that may even include liver failure. Affected patients often suffer from severe itching.

The medicinal product Livmarli helps reduce the accumulation of bile acids in the body, thus relieving patients' itching.

Since PFIC is a rare and life-threatening disease, Livmarli has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Swissmedic first authorised Livmarli on 18 July 2024 for the treatment of cholestatic pruritus in patients aged 3 months and older with Alagille syndrome (ALGS)

Mode of action

Maralixibat, the active substance in the medicinal product Livmarli, blocks a specific bile acid transporter in the intestine. This decreases the reabsorption of bile acids into the body and reduces the accumulation of bile acids in the blood. It is assumed that this mechanism of action can alleviate itching.

Administration

Livmarli is a prescription-only medicine and available as an oral solution at a dose of 9.5 mg maralixibat per mL.

Treatment begins with a once-daily dose of 285 µg/kg body weight.

This dose can be gradually increased if treatment is not sufficiently effective.

The maximum recommended dose for patients aged five years and older is 570 µg/kg twice a day. The maximum recommended dose for patients aged less than five years is 285 µg/kg twice a day. The maximum daily dose for patients over 50 kg is 57 mg.

Livmarli is taken once or twice a day, 30 minutes before a meal.

The physician should check the patient's liver function before starting treatment and continue to monitor it during treatment.

Efficacy

The efficacy of Livmarli was investigated in a study (NCT0390533064) involving a total of 64 patients with PFIC who suffered from itching. The study participants were treated with Livmarli or placebo (dummy drug) for 26 weeks. The results of the study showed that itching was significantly reduced in patients receiving Livmarli compared to the placebo group. 63.6% of patients who received 570 µg/kg Livmarli twice daily achieved a clinically relevant response versus 25.8 % of patients who received placebo.

Furthermore, the reduction in bile acids in the blood was observed to be greater with Livmarli than with placebo.

Precautions, undesirable effects, & risks

Livmarli must not be used in those who are hypersensitive to the active substance or any of the excipients. Furthermore, Livmarli must not be used to treat PFIC in patients with severe hepatic or renal impairment.

The most common undesirable effects are diarrhoea, abdominal pain, blood in the stool and elevated levels of liver enzymes (ALT, AST) in the blood.

All precautions, risks, and other possible side effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

At present, there are only limited drug treatment options for patients with PFIC suffering from cholestatic pruritus.

Study NCT0390533064 showed that Livmarli, containing the active substance maralixibat, can reduce itching in patients aged 12 months and older. No effect on the progression of the underlying disease was demonstrated.

The safety profile was assessed to be acceptable. Given the possible effect on liver function, however, regular checks of liver function parameters are recommended.

Taking all the risks and precautions into account, and based on the available data, the benefits of Livmarli outweigh the risks. Swissmedic has therefore authorised the medicinal product Livmarli, containing the active substance maralixibat, for use in Switzerland for the treatment of cholestatic pruritus in patients with PFIC aged 12 months and older.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Livmarli®

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 into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.