swissmedic

Summary report on authorisation dated 27 January 2026

Hepcludex® (active substance: bulevirtide)

Indication extension in Switzerland: 16 July 2025

Powder for solution for injection for the treatment of chronic hepatitis delta virus (HDV) infections in children three years of age and older weighing at least 10 kg with compensated liver disease

About the medicinal product

The medicinal product Hepcludex contains the active substance bulevirtide.

Hepcludex is an antiviral. It is used to treat long-term (chronic) hepatitis delta virus (HDV) infections in children aged three years of age and older weighing at least 10 kg with compensated liver disease (in which the liver still works well enough) whose plasma (or serum) has tested positive for HDV RNA. Hepatitis delta virus infection results in inflammation of the liver.

Since HDV infection is a rare and life-threatening disease, the medicinal product Hepcludex has been authorised as an orphan drug. "Orphan drug" is a designation given to medicinal products for rare diseases.

Swissmedic first authorised Hepcludex in Switzerland on 5 February 2024 for the treatment of chronic hepatitis delta virus (HDV) infections in adults with compensated liver disease.

Mode of action

HDV uses a specific protein in liver cells to enter the cells. Bulevirtide, the active substance in Hepcludex, blocks this protein, thereby preventing HDV from entering the liver cells. This inhibits the spread of HDV in the liver and relieves inflammation.

Administration

Hepcludex is a prescription-only medicine supplied as a powder for solution for subcutaneous (under the skin) injection.

The dose for children three years of age and older weighing at least 10 kg is determined by body weight: 1 mg daily for children between 10 and 25 kg, 1.5 mg daily for those between 25 and 35 kg and 2 mg daily for those weighing 35 kg and over.

Each vial contains 2 mg bulevirtide. After dissolving in 1 mL sterile water, the concentration of the bulevirtide solution is 2 mg/mL. 0.5 mL, 0.75 mL or 1.0 mL of the solution is administered, depending on the dosage.

Treatment duration is determined by the treating physician.

Efficacy

There are no clinical trial data to demonstrate the efficacy of Hepcludex in children. However, it is known from studies with adults that about half of patients treated with the medicinal product have significantly fewer HDV viruses in their blood after approximately one year and that liver parameters improve at the same time. The results indicate that Hepcludex improves the prognosis of patients with chronic hepatitis D.

In children, the disease follows a similar course to that in adults. The dosage for children was chosen to obtain active substance blood plasma concentrations in the range of those achieved in adults. Treatment results in children are therefore expected to be similar to those in adults.

Precautions, undesirable effects, & risks

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

There are no clinical safety data for children. The most frequent adverse reactions in adults (affecting more than 1 in 10 users) were headache, injection site reactions, pruritus, and increased bile salts. There is a risk of a reduction in fat-soluble vitamins, such as vitamin D, in children with elevated bile salts.

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

The current treatment options for children with chronic hepatitis delta virus infection are extremely limited. There is a lack of high-quality studies in children. This is primarily because the disease is rare.

Hepcludex is regarded as very promising because it prevents the virus entering the liver cells. This inhibits the further spread of the virus. The evidence submitted indicates that the effect in children is similar to that in adults. The efficacy in the treatment of chronic hepatitis delta virus in children can therefore be assumed, based on the proven efficacy in adults.

Taking all the risks and precautions into account, the benefits of Hepcludex outweigh the risks. Swissmedic has therefore authorised the indication extension of Hepcludex in the treatment of chronic HDV infection in children three years of age and older with compensated liver disease in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Hepcludex®

Information for patients (package leaflet): Information for patients Hepcludex®
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.