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Public Summary SwissPAR dated 14 June 2024

# Hepcludex® (active substance: bulevirtide)

First authorisation in Switzerland: 5 February 2024

Powder for solution for injection for the treatment of chronic hepatitis delta virus (HDV) infections in adults 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 adults with liver disease in which the liver still works well enough (compensated liver disease). It should be noted that HDV can only lead to infection in individuals infected with hepatitis B virus (coinfection or superinfection). An infection with the hepatitis delta virus 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.

## 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 injection (under the skin). Each vial contains 2 mg bulevirtide. After dissolving in 1 mL sterile water, the concentration of the bulevirtide solution is 2 mg/mL. Due to solution residues in the syringe and needle, the actual dose of bulevirtide administered is 1.7 mg. The recommended dose is 1 × 2 mg vial of Hepcludex once daily, i.e. 1.7 mg after deduction of residues.

Treatment duration is determined by the treating physician.

## Efficacy

The efficacy of Hepcludex was evaluated in 3 studies (MYR301, MYR202, and MYR203).

A total of 92 patients were treated with the authorised dose of 2 mg Hepcludex once daily.

In study MYR301, patients with chronic HDV infection were randomised either to receive immediate treatment with Hepcludex 2 mg once daily or to only start treatment 48 weeks later.

The aim of the treatment was a combined response with undetectable or significantly reduced HDV RNA (genetic material of the virus) and normalisation of ALT[1] levels.

In study MYR301, 45% of patients treated immediately achieved a combined response after 48 weeks, compared to 2% in the group who started treatment later. 71% of the group treated immediately had undetectable or reduced HDV RNA and 51% had normalised ALT levels.

Studies MYR202 and MYR203 had similar results. It can be deduced from this that Hepcludex 2 mg is effective in patients with chronic HDV infection and compensated liver disease.

## Precautions, undesirable effects, & risks

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

The most frequent adverse reactions (affecting more than 1 in 10 users) are headache, injection site reactions, pruritis, and increased 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 studies performed show that a reduction in HDV viral load and a normalisation of ALT levels was achieved after 48 treatment weeks in 44.9% of patients who received Hepcludex. The results indicate that Hepcludex improves the prognosis of patients with chronic hepatitis D. There is no evidence of development of treatment resistance.

Taking all the risks and precautions into account, and based on the available data, the benefits of Hepcludex outweigh the risks. Swissmedic has therefore authorised Hepcludex in Switzerland for the treatment of chronic HDV infections in adults with compensated liver disease.

## Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Hepcludex®

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

[1] ALT: Alanine aminotransferase (ALT) is an enzyme primarily produced in liver cells. Elevated levels of activity of this enzyme in the blood may indicate liver-related diseases.

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 Public Summary SwissPAR.

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