swissmedic

Public Summary SwissPAR dated 15 December 2023

Veklury® (active substance: remdesivir)

Indication extension in Switzerland: 24 May 2022

Medicinal product (antiviral agent) for the treatment of adults with a disease caused by COVID-19 who are at risk of progression to severe disease

About the medicinal product

The medicinal product Veklury contains the active substance remdesivir. It is supplied as a powder for concentrate for solution for injection. The medicine is injected into the veins.

Veklury is an antiviral medicine (antiviral agent). It is used for the treatment of COVID-19, which is caused by coronavirus.
Veklury was already granted temporary authorisation by Swissmedic on 25 November 2020 for the treatment of patients in hospital with pneumonia who require extra oxygen.

The indication extension means that adults who do not require extra oxygen or in-patient care in hospital and who are at risk of progression to severe COVID-19 can now also be treated with Veklury.

Mode of action

Veklury inhibits RNA polymerase, an enzyme which is important in the production of viral RNA (genetic material of the virus). In doing so, it prevents the virus from multiplying and helps the body to fight the infection.

Use

Veklury, containing the active substance remdesivir, is a prescription-only medicine.

Veklury is available in a dosage strength of 100 mg. Treatment with Veklury should be started as soon as possible after COVID-19 is diagnosed. The initial loading dose is 200 mg on the first day. From the second day of treatment, the dosage is 100 mg once daily. Patients who do not require extra oxygen are treated with Veklury for 3 days. Veklury may only be administered to adults. The safety and efficacy of the medicine in children under 18 years have not yet been established.

Efficacy

The efficacy of Veklury was investigated in 3 different studies for the temporary authorisation in November 2020. Data from another study were also taken into account for the indication extension.

The study concerned (GS-US-540-9012) examined approximately 550 adults with a confirmed diagnosis of COVID-19 and at least 1 risk factor for a severe course of COVID-19. Risk factors were age (over 60 years), chronic lung disease, high blood pressure, cardiovascular disease or cerebrovascular disease, diabetes, obesity, immunodeficiency, kidney or liver disease, current cancer or diseases affecting the red blood cells.

Three-day treatment with Veklury compared to placebo (dummy drug) resulted in a relevant reduction in COVID-19-related in-patient care and the mortality rate.

Precautions, undesirable effects, & risks

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

Undesirable effects of the administration of Veklury can include hypersensitivity reactions to the infusion.

Increased levels of liver enzymes were also observed in the clinical trials with Veklury. Impaired kidney function caused by the administration of Veklury can also not be ruled out. No studies have investigated possible interactions between Veklury and other medicines.

Patients should be under constant medical observation during treatment with Veklury.

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

Why the medicinal product has been authorised

Several medicinal products called monoclonal antibodies with a different mechanism of action are authorised in Switzerland for the treatment of COVID-19 in patients with mild to moderate disease who do not require extra oxygen. However, they are not all effective against the various virus variants. There is therefore still a need for alternative treatment options for this patient group.

The data from the additional study provided evidence of Veklury's benefit in the treatment of COVID-19 in an out-patient setting.

Based on these findings, Swissmedic has approved the indication extension for the medicinal product Veklury for the patient group described.

Further information on the medicinal product

Information for healthcare professionals:
Information for healthcare professionals Veklury®

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.

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.