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Veklury® (active substance: remdesivir)

Temporary authorisation in Switzerland: 25 November 2020

Medicine (antiviral agent) for the treatment of pneumonia caused by COVID-19 and requiring supplemental oxygen.

About the medicinal product

The medicinal product Veklury contains the active substance remdesivir. It is supplied as a concentrate and 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 is only given to patients in hospital with pneumonia who require extra oxygen.

Mode of action

Veklury stops the virus multiplying by blocking the viral 'copying machine' known as RNA polymerase. RNA polymerases are enzymes (proteins) that can read the genetic code and translate it into RNA (ribonucleic acid).

This blocking occurs via the incorporation of a component (remdesivir triphosphate) into the viral RNA. Since this component cannot read RNA polymerase, the virus is no longer able to reproduce.

Use

Veklury, containing the active substance remdesivir, is a prescription-only medicine. The treatment is administered only in hospitals with medical monitoring of the patients.

Veklury is available in a dosage strength of 100 mg. The initial loading dose is 200 mg on the first day. From the second day of treatment, the dosage is 100 mg once daily.

The treatment with Veklury lasts a minimum of 5 and a maximum of 10 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 three different studies.

The largest study comprised 1,062 male and female hospitalised patients with moderate or severe COVID-19. Half of the study participants received a dummy drug (placebo). The other half of the participants received treatment with Veklury. This study showed that the benefit of Veklury was particularly evident in those patients who required supplemental oxygen. The time to recovery was shorter in the severely ill study participants who received Veklury than in those who received placebo. No difference in time to recovery was observed between the Veklury and placebo groups for those patients with mild COVID-19.

Another study with almost 400 male and female patients suffering from severe COVID-19 investigated the treatment period with Veklury. No significant difference in efficacy was observed between a treatment with Veklury over 5 days and a treatment with Veklury over 10 days.

The third study was conducted with almost 600 male and female patients with mild COVID-19. The participants in this study were investigated in respect of differing treatment periods with Veklury (5 and 10 days) compared to traditional types of treatment. The study investigated the improvement in health after 11 days. Those patients who were treated with Veklury for 5 days recovered sooner. The longer 10-day treatment period with Veklury did not produce any improvement in the time to recovery.

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 remain under constant medical observation during their 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

At the time of authorisation of Veklury, no other medicine was authorised in Switzerland for the treatment of COVID-19.

Although the positive efficacy of Veklury has not been demonstrated for all severities of COVID-19, the studies do show that patients who suffer from a severe form of COVID-19 recover sooner with Veklury treatment.

Given the exceptional situation of the pandemic, taking account of all the risks and precautions, and on the basis of the available data, the benefits of Veklury outweigh its risks.

Since the end of June 2020, Veklury has been used in Switzerland on the basis of the version of the COVID-19 Ordinance that was valid at that time.

The medicinal product Veklury was authorised temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical

trials had not yet been concluded at the time of authorisation.

The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been satisfied, this temporary authorisation can be converted into an ordinary authorisation.

Further information on the medicinal product

Information for healthcare professionals:
Information for healthcare professionals Veklury®

Healthcare professionals (doctors, pharmacists and others) can answer any further questions about this medicine.

This information corresponds to that stated in 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.