EMA/791331/2022
EMEA/H/C/005622

Veklury (*remdesivir*)

An overview of Veklury and why it is authorised in the EU

What is Veklury and what is it used for?

Veklury is an antiviral medicine used to treat coronavirus disease 2019 (COVID-19). It is used in adults and children, from at least 4 weeks of age and weighing at least 3 kg, with pneumonia requiring supplemental oxygen (low- or high-flow oxygen or other non-invasive ventilation at the start of treatment).

The medicine can also be used in adults and children (weighing at least 40 kg) who do not require supplemental oxygen and who are at increased risk of developing severe COVID-19.

Veklury contains the active substance remdesivir.

How is Veklury used?

Veklury is given via infusion (drip) into a vein. Treatment for adults and children weighing at least 40 kg should start with a 200mg infusion on the first day, followed by 100mg once a day. In children at least 4 weeks of age and weighing at least 3 kg but less than 40 kg, treatment should start with an infusion of 5 mg per kilogram of bodyweight on the first day, followed by 2.5 mg per kilogram of bodyweight once a day.

In adults and children weighing at least 40 kg with pneumonia requiring supplemental oxygen, the total duration of treatment should be at least 5 days and no more than 10 days. The total duration of treatment for pneumonia requiring supplemental oxygen, in children at least 4 weeks of age and weighing at least 3 kg but less than 40 kg, should not exceed 10 days.

In adults and children weighing at least 40kg who do not require supplemental oxygen, treatment should start as soon as possible after COVID-19 is diagnosed and within 7 days after symptoms appear. The total duration of treatment should be three days.

The medicine can only be obtained with a prescription and its use is limited to healthcare facilities in which patients can be monitored closely.

For more information about using Veklury, see the package leaflet or contact your doctor or pharmacist.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How does Veklury work?

The active substance in Veklury, remdesivir, is a viral RNA polymerase inhibitor. It interferes with the production of viral RNA (genetic material), preventing SARS-CoV-2, the virus that causes COVID-19, from multiplying inside cells. This can help the body to overcome the virus infection and may help patients get better faster.

What benefits of Veklury have been shown in studies?

A main study (NIAID-ACTT-1) involving 1,063 hospitalised patients with COVID-19 (120 with mild to moderate disease and 943 with severe disease) showed that Veklury can speed up the recovery time in some patients, allowing them to spend less time in hospital or on treatment.

The study showed that, in the overall study population, patients treated with Veklury recovered after about 11 days, compared with 15 days for patients given placebo (a dummy treatment). For patients with severe disease requiring supplemental oxygen, time to recovery was 12 days for patients given remdesivir, compared with 18 days for patients on placebo. However, no difference was seen in time to recovery in the subgroup of patients with severe disease who started remdesivir when they were already on mechanical ventilation or ECMO (extracorporeal membrane oxygenation).

The study also showed that, in the overall study population, the mortality rate (the proportion of patients who died) 28 days after treatment started was 11.6% for patients given Veklury and 15.4% for patients on placebo. However, this effect was mainly driven by patients requiring supplemental oxygen in the form of low-flow oxygen at the start of treatment. No beneficial effect of Veklury on mortality was seen in the subgroup of patients with severe disease who started remdesivir when they were already on mechanical ventilation or ECMO.

A separate study (GS-US-540-9012) evaluated the effect of Veklury in 584 non-hospitalised patients who were at high-risk for hospitalisation due to underlying health issues. Treatment with Veklury for 3 days, when started within 7 days of the first appearance of symptoms, reduced the risk of hospitalisation by 87%. Over 28 days, 0.7% of patients treated with Veklury (2 out of 279) were hospitalised compared with 5.3% of patients (15 out of 283) who received placebo.

An additional study (GS-US-540-5823), involving 53 children from 28 days up to less than 18 years of age who were hospitalised with COVID-19, showed that although the level of Veklury and its breakdown products in children were moderately increased compared to those seen in adults, treatment with Veklury was well tolerated and did not result in any new safety concerns in children. The study, which is currently ongoing, did not compare Veklury with other medicines or placebo.

What are the risks associated with Veklury?

The most common side effect with Veklury (which may affect more than 1 in 10 people) in healthy volunteers is raised blood levels of liver enzymes (a sign of liver problems). The most common side effects in patients with COVID-19 is nausea (feeling sick), which may affect up to 1 in 10 people.

For the full list of side effects and restrictions of Veklury, see the package leaflet.

Why is Veklury authorised in the EU?

Veklury showed a clinically meaningful effect on time to recovery in adult and adolescent COVID-19 patients with pneumonia requiring supplemental oxygen, while being well tolerated with mild side effects. Veklury was also effective in preventing hospitalisation in adult and adolescent patients who did not need supplemental oxygen and who were at high-risk of developing severe COVID-19. Veklury

was shown to be absorbed, modified and removed from the body in a similar way in children, as it is in adults; side effects observed in children were also shown to be comparable to those seen in adults. It was therefore considered that Veklury has the same effect in children as it does in adults. The European Medicines Agency therefore decided that Veklury's benefits are greater than its risks and that it can be authorised for use in the EU.

Veklury was originally given 'conditional approval' because there was more evidence to come about the medicine. As the company has supplied the additional information, which confirmed the medicine's activity against different variants of SARS-CoV-2, the authorisation has been switched from conditional to full approval.

What measures are being taken to ensure the safe and effective use of Veklury?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Veklury have been included in the summary of product characteristics and the package leaflet.

A risk management plan for Veklury is also in place, which details important information about the medicine's safety, how to collect further information and how to minimise any potential risks.

As for all medicines, data on the use of Veklury are continuously monitored. Side effects reported with Veklury are carefully evaluated and any necessary action taken to protect patients.

Other information about Veklury

Veklury received a conditional marketing authorisation valid throughout the EU on 3 July 2020. This was switched to a full marketing authorisation on 08 Aug 2022.

Further information on Veklury can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/veklury

This overview was last updated in 10-2022.