



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Xevudy (*sotrovimab*)

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

What is Xevudy and what is it used for?

Xevudy is a medicine used for treating COVID-19 in adults and adolescents (from 12 years of age and weighing at least 40 kilograms) who do not require supplemental oxygen and who are at increased risk of the disease becoming severe.

Xevudy contains the active substance sotrovimab.

How is Xevudy used?

Xevudy is given as a single treatment by infusion (drip) into a vein. The recommended dose is 500 mg given within 5 days of the patient developing symptoms of COVID-19. The medicine can only be obtained with a prescription and should be given in healthcare facilities where patients can be adequately monitored during infusion and for one hour afterwards so that they can be managed in case they develop severe allergic reactions, including anaphylaxis.

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

How does Xevudy work?

The active substance of Xevudy, sotrovimab, is a monoclonal antibody, a type of protein that has been designed to recognise and attach to a specific structure (called an antigen). Sotrovimab has been designed to attach to the spike protein of SARS-CoV-2 (the virus that causes COVID-19). When sotrovimab attaches to the spike protein, the virus is unable to enter the body's cells.

What benefits of Xevudy have been shown in studies?

A main study involving 1,057 patients with COVID-19 and at least one underlying condition putting them at risk of severe COVID-19 showed that Xevudy led to fewer patients requiring hospitalisation or dying within 29 days of treatment when compared with placebo (a dummy treatment). Of the patients at increased risk of their illness becoming severe, 1% of those treated with Xevudy (6 out of 528) were hospitalised for longer than 24 hours within 29 days of treatment compared with 6% of patients on placebo (30 out of 529), 2 of whom died.

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The majority of patients in the study were infected with the original SARS-CoV-2 virus. Some patients were infected with variants including Alpha and Epsilon. Based on laboratory studies, Xevudy is also expected to be active against other variants (including Omicron).

What are the risks associated with Xevudy?

The most common side effects (which may affect between 1 and 2 in 100 patients) are hypersensitivity (allergic) reactions and infusion-related reactions.

The most serious side effect (affecting around 5 in 10,000 patients) was anaphylaxis (severe allergic reaction).

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

Why is Xevudy authorised in the EU?

Xevudy was shown to be effective at reducing the risk of hospitalisation or death in patients with COVID-19 at increased risk of the disease becoming severe. The safety profile of Xevudy is considered favourable. The European Medicines Agency decided that Xevudy's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Xevudy

Xevudy received a marketing authorisation valid throughout the EU on 17.12.2021.

Further information on Xevudy can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/xevudy

This overview was last updated in 12-2021.