Package leaflet: Information for the patient

Xevudy 500 mg concentrate for solution for infusion
sotrovimab

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects, you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any questions, ask your healthcare professional.
- If you get any side effects, talk to your healthcare professional. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Xevudy is and what it is used for

Xevudy contains the active substance sotrovimab. Sotrovimab is a monoclonal antibody, a type of protein designed to recognise a specific target on the SARS-CoV-2 virus, the virus that causes acute covid-19 infection.

Xevudy is used to treat symptomatic acute covid-19 infection in adults and adolescents (from 12 years and weighing at least 40 kg). It targets the spike protein that the virus uses to attach to cells. Xevudy can help your body overcome the infection and prevent you from getting seriously ill.

2. What you need to know before you are given Xevudy

You must not receive Xevudy
- if you are allergic to sotrovimab or any of the other ingredients of this medicine (listed in section 6).

➔ Check with your healthcare professional if you think this applies to you.

Warnings and precautions
You should self-isolate for a period of time after being given Xevudy in accordance with national covid-19 guidelines because you can still pass on the virus to others for some days after treatment.

Allergic reactions
Xevudy can cause allergic reactions (see section 4).

Children and adolescents
Xevudy should not be given to children or adolescents younger than 12 years old or weighing less than 40 kg.

Other medicines and Xevudy

Tell your healthcare professional if you are taking, have recently taken or might take any other medicines. Also tell your healthcare professional if you have been vaccinated against the covid virus or are about to be administered a vaccine.

Pregnancy and breast-feeding
Ask your healthcare professional for advice before receiving Xevudy if you are **pregnant, think you may be pregnant,** or are **planning** to have a baby.

It is not known whether the ingredients of Xevudy can pass into breast milk. Tell your healthcare professional if you are breast-feeding before you receive Xevudy.

Driving and using machines
Xevudy is not expected to have any effect on your ability to drive or use machines.

3. How Xevudy is given

The recommended dose for adults and adolescents (aged 12 years and older and weighing at least 40 kg) is:

- 500 mg (one vial)

The medicine will be made up into a solution and given to you by a drip (infusion) into a vein by a healthcare professional. It takes 30 minutes to give you the full dose of medicine. You will be monitored during and after your treatment is given.

The 'Instructions for healthcare professionals' below give details for your healthcare professional on how the Xevudy infusion is made up and given.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Get urgent medical attention if you get symptoms of a severe allergic reaction (anaphylaxis) after receiving Xevudy. Such reactions may include a combination of any of the following symptoms:

- feeling faint or light-headed, which may lead to loss of consciousness or falls
- shortness of breath or wheezing, difficulty in breathing
- swelling of your lips, face, or throat (angioedema)
- hives or rash (similar to nettle rash)

Other side effects that may occur after receiving Xevudy:

Common (may affect up to 1 in 10 people)

- Less severe allergic (hypersensitivity) reactions including skin rash and itching

Reporting of side effects
If you get any side effects, talk to your healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Xevudy

The healthcare professionals caring for you are responsible for storing this medicine and disposing of any unused product correctly.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP.

Do not freeze.

Before diluting, store in a refrigerator (2°C to 8°C) in original carton to protect from light.

Once diluted, this medicine is intended to be used immediately. If after dilution, immediate administration is not possible, the diluted solution may be stored at room temperature (up to 25°C) for up to 6 hours or refrigerated (2°C to 8°C) for up to 24 hours from the time of dilution until the end of administration.

6. Contents of the pack and other information

What Xevudy contains

- The active substance is sotrovimab. Each vial contains 500 mg of sotrovimab in 8 mL concentrate.
- The other ingredients are histidine, histidine monohydrochloride, sucrose, polysorbate 80, methionine and water for injections.

What Xevudy looks like and contents of the pack
Xevudy is a clear, colourless or yellow to brown liquid supplied in a single-use glass vial with a rubber stopper and flip-off aluminium over-seal. Each carton contains one vial.

Marketing Authorisation Holder
GlaxoSmithKline UK Limited
79 New Oxford Street
London
WC1A 1DG
United Kingdom

Manufacturer
GlaxoSmithKline Manufacturing S.P.A
Strada Provinciale Asolana, No 90
43056 San Polo di Torrile, Parma
Italy

Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK Only)
Please be ready to give the following information:
Product name Xevudy 500 mg concentrate for solution for infusion
Reference number 19494/0301
This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in February 2025.

This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine. The Medicines and Healthcare products Regulatory Agency (MHRA) will review new information on this medicine at least every year and this leaflet will be updated as necessary.

The following information is intended for healthcare professionals only.
Please refer to the Summary of Product Characteristics for further information.

Treatment should be prepared by a qualified healthcare provider. Administration should be under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible. Individuals should be monitored during and post intravenous infusion.

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Preparation for dilution

1. Remove one vial of sotrovimab from the refrigerator (2°C to 8°C). Allow the vial to equilibrate to ambient room temperature, protected from light, for approximately 15 minutes.
2. Visually inspect the vial to ensure it is free from particulate matter and that there is no visible damage to the vial. If the vial is identified to be unusable, discard and restart the preparation with a new vial.
3. Gently swirl the vial several times before use without creating air bubbles. Do not shake or vigorously agitate the vial.

Dilution instructions

1. Withdraw and discard 8 mL from an infusion bag containing 50 mL or 100 mL of sodium chloride 9 mg/mL (0.9%) solution for injection or 5% dextrose for injection.
2. Withdraw 8 mL from the vial of sotrovimab.
3. Inject the 8 mL of sotrovimab into the infusion bag via the septum.
4. Discard any unused portion left in the vial. The vial is single-use only and should only be used for one patient.
5. Prior to the infusion, gently rock the infusion bag back and forth 3 to 5 times. Do not invert the infusion bag. Avoid forming air bubbles.

The diluted solution of sotrovimab is intended to be used immediately. If after dilution, immediate administration is not possible, the diluted solution may be stored at room temperature (up to 25°C) for up to 6 hours or refrigerated (2°C to 8°C) up to 24 hours from the time of dilution until the end of administration.

Administration instructions

1. Attach an infusion set to the infusion bag using standard bore tubing. The intravenous dosing solution is recommended to be administered with a 0.2-µm in-line filter.
2. Prime the infusion set.
3. Administer as an IV infusion for 30 minutes at room temperature.

Disposal
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.