
Patient Information Booklet

For patients who have been
prescribed Xevudy ▼
(sotrovimab)

This booklet has been developed by GSK.
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▼ – Xevudy is subject to additional monitoring. This will allow quick identification of new safety information.

If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in the Patient Information Leaflet or in this booklet.

You can also report side effects directly via the Yellow Card Scheme at <https://coronavirus-yellowcard.mhra.gov.uk/> or search for MHRA Yellowcard in the Google Play or Apple App store.

By reporting side effects you can help provide more information on the safety of this medicine.

Who is this booklet for?

Your healthcare professional has prescribed Xevudy, a medicine containing sotrovimab, for you. This is because you have recently contracted COVID-19. Your healthcare professional knows you may be at an increased risk of developing a more severe infection because of another underlying medical condition you may have.

This booklet gives you more information about your Xevudy treatment. Please refer to the Patient Information Leaflet for further information.

What is Xevudy?

- Xevudy is the brand name for sotrovimab. Sotrovimab is the active substance in this medicine. Sotrovimab is what's called a monoclonal antibody, a type of protein that can recognise a specific target on SARS-CoV-2, the virus that causes acute COVID-19 infection.
- Your healthcare professional uses Xevudy to treat some patients who have symptoms caused by acute COVID-19 infection. Adults and adolescents (from 12 years and weighing at least 40 kg) who have recently developed symptoms and who have tested positive for COVID-19 infection may be eligible to receive Xevudy.
- Xevudy is given (infused) through a drip tube after your doctor or nurse places a needle into one of your veins. The infusion takes half an hour.

Xevudy is a monoclonal antibody

Useful information to know



Why have I been prescribed Xevudy?

Your doctor has prescribed Xevudy for you because you may have an underlying condition putting you at greater risk to have more severe COVID-19 symptoms. You recently had a positive test for COVID-19 and in the last few days have had some symptoms caused by the virus.



How does Xevudy work?

Xevudy belongs to a type of medicine known as a monoclonal antibody also sometimes called a mAb. It works by attaching to the spike protein that sticks out from the coronavirus. The virus uses the spike protein to attach itself to your body's cells and to infect them and then spread to other cells. Xevudy can help your body to fight and overcome the infection and reduce your risk of getting seriously ill.



How is Xevudy given?

Xevudy is given through a drip that goes into one of your veins. These drips are given at NHS sites called COVID Medicines Delivery Units or CMDU or in hospital. Depending on your location, CMDUs are sometimes referred to as Covid Treatment Wards or mAb clinics. You will be monitored during and after your treatment.

What will happen when I go for the Xevudy drip (infusion)?

First, your medicine will be made up into a solution by the medical or nursing team looking after you. It will then be given to you by a drip (infusion) into a vein by your doctor or nurse.

The drip lasts about 30 minutes for you to have the full dose. The nursing and medical staff will keep an eye on you while your treatment is given and for some time afterwards.

The whole process can take 2-3 hours but may be quicker depending on how busy the unit or hospital is when you go for treatment.

1. Before you receive Xevudy:

Once you're comfortable, a healthcare professional will:

- Explain the infusion process and answer any questions you might have.
- Find a vein to use for the drip. This will most likely be in one of your arms.
- The team looking after you will make sure you don't feel unwell or show any signs of a reaction to the treatment such as an allergy to the medicine.

2. While you are receiving the drip (infusion):

- If you feel any side effects, you should let your healthcare team know straight away. Please refer to page 5 to understand what side effects are possible.

3. What happens when the drip is finished?

- The doctor or nurse will ask you to stay in the unit for a while after the drip finishes to make sure you feel well and are medically ok. Once they are happy with everything you will get the thumbs-up to go home.
- Because you tested positive for coronavirus, you may need to self-isolate at home depending on the advice of your doctors and the COVID-19 guidelines currently in place. This is because you could still pass on the virus to others for some time even after receiving treatment.

What else do I need to know about Xevudy?

Who should not take Xevudy?

You should not be given Xevudy if you are allergic to sotrovimab or any of the other ingredients in this medicine.

Check with your healthcare professional if you think this could apply to you.

Xevudy contains the following ingredients:

The active medicine is the sotrovimab antibody treatment. Xevudy also contains histidine, histidine monohydrochloride, sucrose, polysorbate 80, methionine and water for injections.

It is also important to know about:

- **Allergic reactions:** Xevudy can cause allergic reactions (see section below 'Possible side effects').
- **Children and adolescents:** Xevudy should not be given to children or adolescents younger than 12 years old or anyone who weights less than 40kg.
- **Other medicines and Xevudy:** Tell your healthcare professional if you are taking, have recently taken or might take other medicines. Also tell your healthcare professional if you have been vaccinated against the COVID-19 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.
- **Drive and using machines:** Xevudy is not expected to have any effect on your ability to drive or use machines.

What side effects are possible?

Like any medicine, this medicine can cause side effects, although not everybody gets them. For more information please refer to the Patient Information Leaflet.

Allergic (hypersensitivity) and infusion reactions are possible side effects of Xevudy

These usually happen within the first 24 hours after receiving treatment.

Although rare, it is possible for patients to get severe allergic reactions (anaphylaxis) after receiving Xevudy. This side effect is **rare** and can affect up to **1 in 1,000 people**.

Get urgent medical attention if you get symptoms of anaphylaxis, which can 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)

The **most common** side effect that has been seen is a less severe allergic (hypersensitivity) reaction. This can include skin rash and itching. This side effect is **common** and may affect up to **1 in 10 people**.

What should I do if I have a side effect?

If you get any side effects, please discuss these with your healthcare professional. This includes any possible side effects not mentioned already in this booklet.

You can also report side effects directly via the system set up by the MHRA, the Government Agency responsible for regulating and licensing medicines. You can go to the Yellow Card Scheme website <https://coronavirus-yellowcard.mhra.gov.uk/> or search 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.

Additional questions you might have



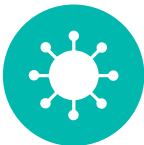
How long will it take for Xevudy to work and for me to feel better?

It is not possible to be certain about how long it will take for you to feel better on Xevudy, and not every medicine is effective in every patient.



Do I need to isolate after receiving Xevudy?

Because you have tested positive for coronavirus, you may need to self-isolate at home depending on the advice of your doctors and the COVID-19 guidelines currently in place. This is because you could still pass on the virus to others for some time even after receiving treatment.



Can I get COVID-19 again after receiving treatment and would I get Xevudy again?

Yes, it is possible for you to catch COVID-19 again despite receiving Xevudy. If you are concerned that this might happen to you, please talk to your doctor or nurse as they will be able to advise you as to what you should do in this situation.

Always speak to your healthcare professional if you have any questions or concerns

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