

XEVUDY Concentrated injection solution for infusion

XEVUDY has **provisional approval** for treatment of COVID-19 in adults and adolescents (aged 12 years and over and weighing at least 40 kg) with coronavirus disease 2019 (COVID-19) who do not require initiation of oxygen due to COVID-19 and who are at increased risk of progression to hospitalisation or death. This approval has been granted on the basis of short term efficacy and safety data. Evidence of longer term efficacy and safety from ongoing trials continues to be gathered and assessed.

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I being given XEVUDY?

XEVUDY contains the active ingredient sotrovimab. XEVUDY is used to treat COVID-19.

For more information, see Section [1. Why am I being given XEVUDY?](#) in the full CMI.

2. What should I know before I am given XEVUDY?

Do not use if you have ever had an allergic reaction to sotrovimab or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I am given XEVUDY?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with XEVUDY and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How XEVUDY is given?

- XEVUDY should not be given to you if you have been hospitalised due to COVID-19.
- The recommended dose for adults and adolescents aged 12 years and older and weighing at least 40 kg is one 500 mg dose of XEVUDY.
- XEVUDY is recommended to be given to you within 5 days of showing symptoms of COVID-19.

- It is given as a drip into a vein (intravenous infusion) by a doctor or nurse. It takes 30 minutes to give you the full dose of medicine.

More instructions can be found in Section [4. How XEVUDY is given?](#) in the full CMI.

5. What should I know when being given XEVUDY?

<p>Things you should do</p>	<ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that you have taken XEVUDY. • Seek medical attention if you think you may be having an allergic reaction.
<p>Things you should not do</p>	<ul style="list-style-type: none"> • Do not stop before the full dose of medicine is taken.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> • XEVUDY is not expected to have any effect on your ability to drive or use machines.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> • XEVUDY will be given to you in a healthcare facility and the healthcare professionals will be

	responsible for its storage.
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For more information, see Section [5. What should I know when being given XEVUDY?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some of the side effects can be serious, and you need to know what symptoms to look out for. XEVUDY can cause allergic reactions which may be severe. If you develop symptoms of an allergic reaction, you must tell your doctor or nurse as soon as possible. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

XEVUDY Concentrated injection solution for infusion

Active ingredient: *sotrovimab*

XEVUDY has **provisional approval** for treatment of COVID-19 in adults and adolescents (aged 12 years and over and weighing at least 40 kg) with coronavirus disease 2019 (COVID-19) who do not require initiation of oxygen due to COVID-19 and who are at increased risk of progression to hospitalisation or death.

This approval has been granted on the basis of short term efficacy and safety data. Evidence of longer term efficacy and safety from ongoing trials continues to be gathered and assessed.

Consumer Medicine Information (CMI)

This leaflet provides important information about using XEVUDY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using XEVUDY.**

Where to find information in this leaflet:

- [1. Why am I being given XEVUDY?](#)
- [2. What should I know before I am given XEVUDY?](#)
- [3. What if I am taking other medicines?](#)
- [4. How XEVUDY is given?](#)
- [5. What should I know when being given XEVUDY?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given XEVUDY?

XEVUDY contains the active ingredient sotrovimab, a monoclonal antibody which is a type of protein designed to recognise a specific target on the SARS-CoV-2 virus, the virus that causes COVID-19 .

XEVUDY is used to treat COVID-19.

XEVUDY stops the virus from attaching to cells and this blocks the virus from multiplying in the body. This can help your body to overcome the infection and prevent you from getting seriously ill.

2. What should I know before I am given XEVUDY?

Warnings

Do not take XEVUDY if:

- you are allergic to sotrovimab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes. XEVUDY can cause allergic reactions.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or think you could be pregnant or intend to become pregnant and discuss if you should receive XEVUDY. Your doctor will

consider the benefit to you and the risk to your baby of receiving XEVUDY while you're pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. There is insufficient data on whether the ingredients of XEVUDY can pass into breast milk. If you are breast-feeding, you must check with your doctor before you receive XEVUDY.

Children

XEVUDY is not intended to be given to children younger than 12 years old or weighing less than 40 kg.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect XEVUDY.

4. How XEVUDY is given?

XEVUDY should not be given to you if you have been hospitalised due to COVID-19.

How much is given

The recommended dose for adults and adolescents aged 12 years and older and weighing at least 40 kg is one 500 mg dose of XEVUDY.

When XEVUDY is given

- XEVUDY is recommended to be given to you within 5 days of showing symptoms of COVID-19.
- XEVUDY will be given to you in a healthcare facility under the supervision of a healthcare professional.
- It will be given to you as a drip into a vein (intravenous infusion).
- It takes 30 minutes to give you the full dose of medicine.
- After the infusion, your doctor or nurse will observe you for 1 hour to monitor for signs of an allergic reaction.

5. What should I know when being given XEVUDY?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that have taken XEVUDY.
- Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines before you receive XEVUDY.

- Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.

Call your doctor straight away if you:

- Think you may be having an allergic reaction
- Notice any symptoms listed in Section [6. Are there any side effects?](#)

Things you should not do

- Do not stop your medicine before the full dose has been taken.

Driving or using machines

XEVUDY is not expected to have any effect on your ability to drive or use machines.

Looking after your medicine

XEVUDY will be given to you in a healthcare facility and the healthcare professionals caring for you will be responsible for storing this medicine.

XEVUDY should be stored in a refrigerator between 2°C to 8°C, in the original carton to protect from light.

- Do not freeze
- Do not use after the expiry date

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

Unused medicine or waste material will be discarded by your healthcare professional.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
<p>Allergic reactions</p> <p>These reactions may be severe (for example anaphylaxis) with the following symptoms:</p> <ul style="list-style-type: none">● skin rash (hives) or redness● swelling, sometimes of the face or mouth (angioedema)	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>These side effects can have a delayed onset after you leave the infusion site or clinic.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● becoming very wheezy, coughing or having difficulty in breathing ● suddenly feeling weak or light-headed (may lead to loss of consciousness or falls) 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What XEVUDY contains

Active ingredient (main ingredient)	Sotrovimab
Other ingredients (inactive ingredients)	Histidine Histidine hydrochloride monohydrate Sucrose Methionine Polysorbate 80 Water for injections
Potential allergens	None

Do not be given this medicine if you are allergic to any of these ingredients.

What XEVUDY looks like

XEVUDY is supplied as a clear, colourless or yellow to brown concentrated injection solution, in a 10 mL clear glass vial, with a rubber stopper and flip-off aluminium over-seal.

(Aust R 364110).

Who distributes XEVUDY

XEVUDY is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street

Abbotsford, VIC 3067

Australia

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