



Sotrovimab (Xevudy®)

Patient Information

This information leaflet includes important information about the medicine called sotrovimab when used in the treatment of COVID-19.

NOTE: Having COVID-19 infection and being treated does not offer the same protection as vaccination.

What is the medication used for?

Sotrovimab has been provisionally approved in Australia to treat mild to moderate COVID-19 in people who do not need oxygen but are at risk of COVID-19 becoming more severe. The brand name is Xevudy®. A recent clinical trial has studied how well Sotrovimab works in treating COVID-19. Australia's National COVID-19 Clinical Evidence Taskforce has made recommendations about when Sotrovimab is most likely to work / not work in the treatment of COVID-19.

What does this medication do?

Sotrovimab belongs to a group of medicines called monoclonal antibodies. Sotrovimab has been developed for the treatment of COVID-19. It works by binding to the spike protein of the virus that causes COVID-19. This binding blocks the virus entering human cells and multiplying in the body. The results of a recent study indicate it probably reduces your risk of being admitted to hospital or dying if used within 5 days of onset of symptoms of COVID-19.

What should be considered when using Sotrovimab in COVID-19?

Because sotrovimab is a new medicine, information about how well it works and how safe it is, is currently being collected. It is important that patients and their carers understand when and why sotrovimab may be useful. Your health practitioner will provide more information about how well it works and how safe it is for your condition.

Because the use of sotrovimab is new, it is important for you to provide your formal consent before receiving sotrovimab. You can always change your mind about treatment with sotrovimab and withdraw your consent at any time.

What are the side effects of sotrovimab?

All medicines have side effects. Sometimes they are serious, but most of the time they are not, and many side effects disappear with time or when treatment is stopped. Medical treatment may be needed with some side effects. Some people will not experience side effects. There is also the possibility of experiencing other unknown side effects with Sotrovimab when it is used in people with COVID-19.

What should the health practitioner know before sotrovimab is used in COVID-19?

The health practitioner should know about:

- any medical conditions you have
- previous allergic reactions to any medicine
- all medicines including over-the-counter and complementary medicines e.g. vitamins, minerals, herbal or naturopathic medicines that you are taking or have recently taken
- the possibility of pregnancy or plans for pregnancy
- recent vaccinations or plans to get vaccinated

Some possible side effects that might be experienced during treatment with Sotrovimab for COVID-19 are shown below.

Possible side effects of Sotrovimab	What to do
<ul style="list-style-type: none"> • Skin redness or rash (hives) • Diarrhoea 	<p>Tell your health practitioner or nurse if these symptoms occur and they can help treat them.</p>
<ul style="list-style-type: none"> • Non-allergy reactions while you are receiving the Sotrovimab infusion; symptoms may include: <ul style="list-style-type: none"> ○ fever or chills ○ chest pain or pressure ○ fast, slow, or abnormal heartbeat ○ upset stomach ○ headache or dizziness ○ throat irritation or shortness of breath ○ itchiness and rash 	<p>Immediately tell your health practitioner if these symptoms occur.</p>
<ul style="list-style-type: none"> • Allergic reaction symptoms may include: <ul style="list-style-type: none"> ○ feeling short of breath, wheezing, difficulty breathing ○ swelling of the face, lips, tongue, or other parts of the body ○ severe skin rash, itching, hives 	<p>Immediately tell your health practitioner if these symptoms occur.</p>

Please note: This is not a complete list of all possible side effects. A link to find out more information on the side effects of sotrovimab is listed at the end of this information leaflet. Also, your health practitioner can provide a more complete list of side effects.

Side effects can be reported to the health practitioner directly and/or to the Therapeutic Goods Administration at www.tga.gov.au/reporting-problems.

If you are experiencing any side effects, including any of the ones listed above or are feeling unwell in any way, please call the health practitioner on the phone number below for advice.

Name of health practitioner to call:	
Telephone number:	

How is Sotrovimab given?

Sotrovimab is given by infusion into a vein (intravenous administration) by a doctor or nurse. The infusion normally takes about 30 minutes and will be given in a healthcare setting serviced by hospital staff.

The recommended dose is a single dose of 500 mg.

You will be observed by the nurse or doctor for one hour after receiving sotrovimab to make sure you do not have an allergic reaction.

Are there special precautions with Sotrovimab treatment?

Use with Other Medicines

Sotrovimab is a new medicine. So far, no medicine interactions have been identified for sotrovimab in any clinical trials. However, it is important that the doctors and other health practitioner (such as the pharmacist or nurse) are informed about all medications normally taken or planned. This includes over-the-counter and complementary medicines e.g. vitamins, minerals, herbal or naturopathic medicines.

The health practitioner will check for medicine interactions before sotrovimab is started and when it is stopped.

Vaccinations

There is currently limited information about the effect sotrovimab may have on any recent vaccinations you have had, including any COVID-19 vaccination. This treatment may reduce your response to vaccines given within 90 days (before or after) treatment with sotrovimab. Make sure you tell the health practitioner about any of your recent vaccinations. Consult your health practitioner about future vaccinations and their timing, including any COVID-19 vaccinations.

Fertility, Pregnancy and Breastfeeding

- Further studies about using sotrovimab in pregnancy and breastfeeding are underway. Consult your doctor or pharmacist for information and advice.
- Currently, the effect of sotrovimab on fertility is unknown.

For further information about the use of this medicine in pregnancy, breastfeeding or family planning, please contact the King Edward Memorial Hospital Obstetric Medicines Information Service on 6458 2723.

What should I do if my COVID-19 symptoms get worse?

Call your healthcare provider if you have any questions or concerns.

Call 000 immediately if you experience severe symptoms of COVID-19, such as:

- difficulty breathing
- severe chest pain
- feelings of disorientation or confusion
- loss of consciousness

If you have any questions about this medication, call your health practitioner.

What should I do after I finish my treatment?

Treatment does not shorten your isolation time. You are still considered to be contagious while you are taking your treatment. Follow all Public Health guidelines for isolation. For information about isolation please refer to the Healthy WA website.

https://www.healthywa.wa.gov.au/Articles/A_E/Coronavirus/Quarantine-and-isolation

More information on Sotrovimab?

- GlaxoSmithKline Australia Pty Ltd. Australian Consumer Medicines Information Xevudy® Concentrated injection solution for infusion (sotrovimab). Therapeutic Goods Administration. Published August 2021.
https://search.tga.gov.au/s/search.html?collection=tga-artg&profile=record&meta_i=364110
- National COVID-19 Clinical Evidence Taskforce. Australian Guidelines for the Clinical Care of people with COVID-19. <https://covid19evidence.net.au/#living-guidelines>

This document can be made available in alternative formats on request for a person with disability.

© Department of Health 2022

Copyright to this material is vested in the State of Western Australia unless otherwise indicated. Apart from any fair dealing for the purposes of private study, research, criticism or review, as permitted under the provisions of the *Copyright Act 1968*, no part may be reproduced or re-used for any purposes whatsoever without written permission of the State of Western Australia.

Adapted from NSW Therapeutic Advisory Group Inc., *Use of sotrovimab in adults with COVID-19 | Patient Information Leaflet*