

## USE OF SOTROVIMAB IN ADULTS WITH COVID-19

### INFORMATION FOR PATIENTS, FAMILIES AND CARERS

This information leaflet has important information about the medicine called sotrovimab when used to treat COVID-19.

#### WHAT IS THE POTENTIAL BENEFIT OF SOTROVIMAB FOR COVID-19?

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 the risk of being admitted to hospital or dying if used within 5 days of onset of symptoms of COVID-19.

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 COVID-19. Australia's [National COVID-19 Clinical Evidence Taskforce](http://www.nswtag.org.au/resources-for-experimental-medicines-for-the-treatment-of-covid-19/) has made recommendations about when sotrovimab is most likely to work and not work in the treatment of COVID-19.

#### WHAT SHOULD BE CONSIDERED WHEN USING SOTROVIMAB IN COVID-19?

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

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

#### WHAT SHOULD THE DOCTOR KNOW BEFORE SOTROVIMAB IS USED IN COVID-19?

The doctor 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

## 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 of them disappear with time or when treatment is stopped. Medical treatment may be needed with some side effects. Side effects may not be experienced. Some possible side effects that might be experienced during treatment with sotrovimab for COVID-19 are shown below. There is a possibility of experiencing other unknown side effects with sotrovimab when it is used in people with COVID-19.

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

**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, the doctor, pharmacist or nurse can provide a more complete list of side effects. Side effects can be reported to the doctor directly and/or to the Therapeutic Goods Administration at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

<b>If you are experiencing any side effects, including any of the ones listed above or are feeling unwell in any way, please call the healthcare worker on the phone number below for advice.</b>	
 <b>Name of healthcare worker to call:</b>	
 <b>Telephone number:</b>	

## 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 to sotrovimab.

## 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 professionals (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 doctor and pharmacist will check for medicine interactions before sotrovimab is started and when it is stopped.

### Vaccinations

There is currently no information about the effect sotrovimab may have on any recent vaccinations you have had, including any COVID-19 vaccination.

Make sure you tell the doctors about any of your recent vaccinations. Consult your doctor about future vaccinations and their timing, including any COVID-19 vaccinations.

### Fertility, Pregnancy and Breastfeeding

- Currently it is not recommended that sotrovimab is used in pregnant and breastfeeding women who have COVID-19. Consult your doctor or pharmacist for information and advice.
- The effect of sotrovimab on fertility is unknown.

My notes:

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## 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](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>

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This Information Leaflet is provided to support clinicians if sotrovimab is used outside a trial setting. See <http://www.nswtag.org.au/resources-for-experimental-medicines-for-the-treatment-of-covid-19/> for further details.