Information for patients, family and carers

Use of sotrovimab injection for the treatment of COVID-19

This information leaflet contains important information about the medicine sotrovimab (available as the brand Xevudy®) 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. It works by blocking the virus that causes COVID-19 from entering human cells and multiplying in the body.

This medicine is not a replacement for vaccination against COVID-19.

Studies found that when people took sotrovimab within 5 days of showing symptoms of COVID, it reduced their chances of:

- getting very sick with COVID-19
- being admitted to hospital
- dying from COVID-19.

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

In Australia, sotrovimab has provisional (temporary) approval to treat COVID-19 as it is a recent treatment. *Short-term* safety data shows it is safe to use. *Long-term* safety data is still being collected. It is important that patients and their carers understand when and why sotrovimab may be useful. Your doctor will provide more information about how well it works and how safe it is for your circumstances.

As this is still a new treatment for COVID-19, you should talk to you doctor if you have any questions or concerns. It is important to feel comfortable with the answers before giving your permission to use sotrovimab. You can always change your mind and take back permission at any time.

What should your doctor know before sotrovimab is used for COVID-19?

It is important for your doctor to know your medical history before giving you sotrovimab. They may ask about:

- any past allergic reactions to medicines
- any medical conditions you have (e.g., diabetes/high sugar, high blood pressure, asthma)
- all medicines you take including prescription medicines, vitamins, herbal or naturopathic medicines
- if you may be pregnant, breastfeeding or are planning to have a baby soon
- recent vaccinations or plans to get vaccinated.

How is sotrovimab given?

Sotrovimab is given by a needle into a vein (intravenous administration) by a doctor or nurse. The infusion takes about 30 minutes, and you will be observed by the health care worker for one hour afterwards to make sure you do not have a reaction to it (will be explained below).

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What are the side effects of sotrovimab?

You may not get any side effects when taking sotrovimab. The most common side effects reported by patients with COVID-19 are listed in the table below. There is also a chance you may get unknown side effects.

Possible side effects of sotrovimab	What to do
Side effects which may appear after receiving sotrovimab:	Tell your doctor, pharmacist or nurse if this
Skin redness or rash	happens as they can help.
Diarrhoea	
Reactions that may occur when sotrovimab infusion is given include: • Fever or chills • Chest pain or pressure • Fast, slow, or abnormal heartbeat • Upset stomach • Headache or dizziness	Immediately tell your doctor, pharmacist or nurse if these symptoms occur.
 Throat irritation or shortness of breath Itchiness and rash 	
Allergic reactions, symptoms may include: • Feeling short of breath, wheezing, difficulty breathing • Swelling of the face, lips, tongue or other parts of the body • Severe skin rash, itching, hives	If you are at home or in the community – Contact 000 or go straight to the Emergency Department at your nearest hospital. If in the hospital or outpatient setting – Immediately tell the doctor, pharmacist or nurse if these symptoms occur.

Please note: This is not a complete list of all side effects. Because sotrovimab is a new medicine, it is important to report side effects to the doctor directly and/or to the <u>Therapeutic Goods Administration</u>.

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

Name of healthcare worker to call:	
Telephone number:	_
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Are there special precautions with sotrovimab treatment?

Use with other medicines

Sometimes medicines can interact with each other and cause problems. Sotrovimab is a new medicine and studies have not found any medicines that interact with sotrovimab. However, it is important that you tell your doctor and other health professionals (like the pharmacist or nurse) about all medications you normally take or plan to take. This includes over the counter and complementary medicines e.g., vitamins, minerals, herbal or naturopathic medicines that you are taking or have recently taken. The doctor and pharmacist will check for any medicine interactions before sotrovimab is started and when it is stopped.

Fertility, pregnancy and breastfeeding

- The effect of sotrovimab on fertility (ability to have a baby) is unknown.
- There is not enough information yet on how sotrovimab affects human pregnancy. In pregnant women, sotrovimab probably passes to the baby but we don't know if this is completely safe. Because COVID-19 can be very serious for pregnant women and their babies, doctors may recommend sotrovimab if the mother has other conditions that increase her chances of becoming very sick with COVID-19. It is important to speak with your doctor and make sure you are comfortable before receiving sotrovimab.
- There is not enough information on whether sotrovimab passes into human breast milk. Your doctor may tell you to stop breastfeeding during sotrovimab treatment. If you are breastfeeding or planning to breastfeed, it is best to discuss this with your doctor before receiving sotrovimab.
- Advice may change if new evidence comes out. Speak with your doctor or pharmacist for the most recent advice on sotrovimab use in pregnant and breastfeeding women.

<u>Vaccinations</u> – There is not much information about what effect sotrovimab may have on any recent vaccinations you have had, including any COVID-19 vaccination. If you are due to have any vaccinations soon, let your doctor know and they will tell you when it is safe to have them.

More information for sotrovimab

- Consumer Medicines Information: Xevudy® (sotrovimab)
- Call the NPS Medicines Line 1300 633 424

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