

Information for patients, family and carers

Use of sotrovimab (Xevudy®) for the treatment of COVID-19 in pregnancy

This information leaflet contains important information about the medicine sotrovimab (available as the brand Xevudy®) when used to treat COVID-19 in pregnancy.

Why is sotrovimab being offered to pregnant women?

Pregnant women with COVID-19 have a **higher chance of becoming very sick from COVID-19** compared to women who are not pregnant.

The chances of becoming sick or dying from COVID-19 infection are higher if a woman has other health conditions, including obesity, diabetes, asthma, or other serious health problems.

Pregnant women who do become severely unwell from COVID-19 are more likely to have pregnancy complications such as pre-eclampsia, preterm birth or stillbirth.

Has sotrovimab been studied in pregnant women?

Pregnant women have been receiving sotrovimab to prevent severe COVID-19 infection around the world since mid-2021. However, pregnant women were not included in the research trials of sotrovimab. The lack of trials in pregnant women does not mean that it is harmful to pregnant women or their babies, but it does mean that we do not have published safety data for this particular medication.

What is the potential benefit of sotrovimab for COVID-19?

Sotrovimab 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.

Sotrovimab is of most benefit to patients with risk factors for progressing to severe COVID-19 disease.

As new variants emerge, the effectiveness of this medicine may change. Speak with your doctor about whether this treatment is right for you. .

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

In Australia, sotrovimab has provisional (temporary) approval to treat COVID-19 from the Therapeutic Goods Administration (TGA) since August 2021. *Short-term* safety data shows it is safe to use. *Long-term* safety data is still being collected.

There is experience with the use of similar medications in pregnancy. We have not seen any adverse effects from these medications on the pregnancy or in the baby. As this is still a new treatment for COVID-19, you should talk to you doctor if you have any questions or worries. You can always change your mind and decide not to have this medicine at any time.

Can sotrovimab cross the placenta to my baby?

It is expected that very small amounts of sotrovimab will cross the placenta to your unborn baby. Sotrovimab may protect your baby from COVID-19, but this has not been proven yet.

Other similar medicines are given during pregnancy for different reasons and are safe.

Can sotrovimab be used in breastfeeding?

Based on our knowledge of the medicine and other similar medicines, it is expected that sotrovimab will only pass through to human milk in tiny amounts. Your baby will not be able to absorb a lot of this medicine into their body, and so it is unlikely to cause any side effects in your baby.

Women with COVID-19 are encouraged to continue breastfeeding.

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

Apart from your pregnancy, your doctor should know about:

- any medical conditions you have, including any kidney or liver problems
- 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
- if you are breastfeeding or plan to breastfeed
- recent vaccinations or plans to get vaccinated.

How is sotrovimab given?

Sotrovimab is given by a drip into a vein (intravenous administration) by a doctor, nurse or midwife. 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.

It must be given within 5 days of symptom onset.

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 so far, 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, midwife 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.

Vaccinations – there is not much information about what effect sotrovimab may have on any recent vaccinations you have had, including any COVID-19 vaccination. Make sure you tell the health care workers about any of your recent vaccinations and any future vaccinations.

Information for patients, family and carers

Use of sotrovimab (Xevudy®) for the treatment of COVID-19 in pregnancy

What are the side effects of sotrovimab?

You may not get any side effects when taking sotrovimab. Some of the 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: <ul style="list-style-type: none">• Skin redness or rash• Diarrhoea	Tell your doctor, midwife or nurse if these symptoms occur.
Reactions that may occur during the sotrovimab infusion 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	Immediately tell your doctor, midwife or nurse if these symptoms occur.
Allergic reactions are rare , however you should look out for the following symptoms: <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	If in the community setting – Contact 000 or go straight to the Emergency Department at your nearest hospital. If in the hospital or outpatient setting – Immediately tell the doctor, midwife, or nurse if these symptoms occur.

Please note: This is not a complete list of all possible side effects. Because sotrovimab is a new medicine, it is important to report side effects to the doctor directly and/or to the [Therapeutic Goods Administration](#).

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.

Name of healthcare worker to call: _____
Telephone number: _____

For more information about sotrovimab

- [Consumer Medicines Information: Xevudy® \(sotrovimab\)](#)
- Call MotherSafe (a free telephone service for the women of NSW) – 9382 6539 or 1800 647 848 (Non-Metropolitan Area)
- Call the [NPS Medicines Line](#) – 1300 633 424