

Sotrovimab for treatment of COVID-19 in pregnancy

Who is this information for?

This important information is for pregnant women who have recently become infected with COVID-19 and are considering treatment with the medicine called sotrovimab.

What is Sotrovimab?

Sotrovimab is a medication that protects people who have been recently infected with COVID-19.¹

Sotrovimab stops the COVID 19 virus from entering your body's cells. This makes it less likely that you will get very sick with Covid-19. Sotrovimab provides immediate protection from COVID-19.

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

- Sotrovimab has been developed for the treatment of COVID-19.
- If given in the first 5 days of COVID-19 infection, sotrovimab may reduce the chances of being admitted to hospital or dying by up to 85%.
- For a non-vaccinated pregnant woman with symptoms of COVID-19, the chance of dying with COVID-19 after treatment with sotrovimab is 6 times lower. This means the chance of dying is reduced from 1 in 62 to 1 in 400.^{2,3}
- You will need to provide consent (approval) before you receive the medication. As part of this process, the doctor will discuss the potential benefits as well as any risks with you. You can always change your mind about treatment with sotrovimab and withdraw consent at any time.

How is sotrovimab given?

- Sotrovimab is given into a vein (intravenous administration) by a doctor or nurse and normally takes about 30 minutes.
- You will be observed by the nurse or doctor for one hour after receiving sotrovimab to make sure that you do not have an allergic reaction.
- After this, you will be able to go home if you are feeling well.

For more information: [Infusion Clinic | Monash Health](#)

What are the side effects of sotrovimab?

Most people who receive sotrovimab do not experience side effects. However, you should be aware that some possible side effects are:

Common side effects (between 1 in 100 patients and 1 in 10 patients)

- Non-allergic reactions while receiving the sotrovimab infusion:
 - fever or chills
 - chest pain or pressure

- fast, slow or abnormal heartbeat
- upset stomach or diarrhoea
- headache or dizziness
- throat irritation or shortness of breath
- itchiness and mild skin rash (hives).
- Allergic reactions:
 - feeling short of breath, wheezing, difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - severe skin rash, itching, hives.

There is a possibility of experiencing other unknown side effects with sotrovimab that are not listed above.

If you experience any side effects tell the doctor or nurse immediately.

Sotrovimab is currently used in the United States, Europe and Australia.

Why is it being offered to pregnant women?

Pregnant women with COVID-19 have a higher chance of becoming very sick compared to non-pregnant women. About 1 in 12 pregnant women who become sick with COVID-19 require intensive care, and about 1 in 62 women may die.²

The chances may be even 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 preterm birth or stillbirth.

Has it been studied in pregnant women?

Pregnant women have been receiving sotrovimab to prevent severe COVID-19 infection around the world for months. However, pregnant women were not included in the research trials of sotrovimab. The lack of trials in pregnant women do 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.

We do have a lot of experience with similar medications in pregnancy (the 'monoclonal antibodies'). Monoclonal antibodies have been used by pregnant women for many years, and we have not seen any adverse effects on the pregnancy or in the baby.

Can sotrovimab cross the placenta to my baby?

We think that the antibodies in sotrovimab will cross the placenta to your unborn baby.

Sotrovimab may protect your baby from COVID-19, but this has not been proven yet.

What are the Australian recommendations on sotrovimab in pregnancy?

The Australian COVID-19 National Taskforce¹ recommends that:

Sotrovimab should be considered for the treatment of COVID-19 within 5 days of symptom onset in pregnant women in the second or third trimester who do not require oxygen and who have one or more additional risk factors for disease progression.

Pregnant women with the following conditions are eligible for sotrovimab:

- *pre-pregnancy diabetes requiring medication*
- *obesity (BMI >30)*
- *chronic kidney disease*
- *congestive heart failure*
- *chronic lung disease*
- *moderate to severe asthma.*

Are there special precautions with sotrovimab?

Vaccination:–

- It is recommended that you do not receive your COVID-19 vaccination for at least 3 months (90 days) after receiving sotrovimab. You will be provided with a medical exemption letter for this 90 day period.
- It is very likely sotrovimab and your COVID-19 infection will prevent you from getting COVID-19 again within these 3 months (90 days).
- Your doctor will be able to provide advice about other vaccines.

What do I need to do after I have had my dose of sotrovimab?

- Continue to follow the health advice provided by the team who are providing your COVID-19 care and the Department of Health. Monitor for the symptoms of COVID-19, as they may still occur.
- If you start to feel unwell or your symptoms get worse but are not serious, report these to the team who are providing your COVID-19 care (GP or local COVID-19 Care Pathway). Alternatively, please call the COVID-19 hotline.
- If you have serious symptoms, like difficulty breathing, call 000 and ask for an ambulance. Make sure you say that you have COVID-19 and are in isolation.
- If anyone else you are living with developed symptoms – no matter how mild – they should get tested and isolate. The Department of Health will tell them when they can stop isolating.
- If you think you have developed a possible side effect from the sotrovimab, contact the team who are providing your COVID-19 care (GP or local COVID-19 Care Pathway). Alternatively, please call the COVID-19 hotline.

Please talk with your doctor if you have any further questions.

What are the chances of severe complications for pregnant women who have symptoms or chest X-ray changes of COVID-19?²

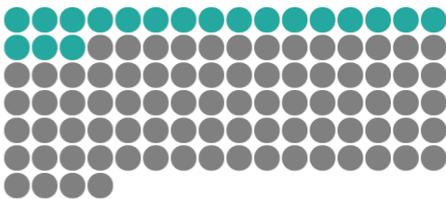
Risk of intensive care admission is 8.3% or 1 in 12. This is about 5 times higher than the chance of ICU admission compared to pregnant women without COVID-19.

8.3%



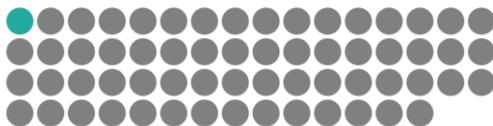
Risk of medically-indicated preterm birth is 19% or 1 in 5. This is nearly double the chance of preterm birth compared to pregnant women without COVID-19.

19%



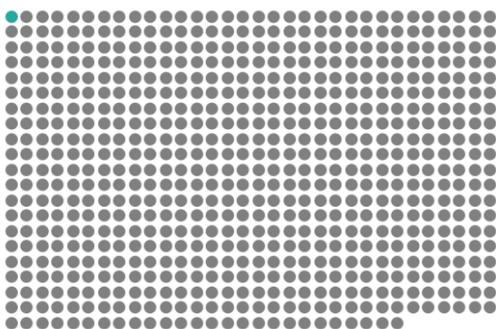
Chance of maternal death without sotrovimab is 1.6% or 1 in 62. This is more than 22 times the chance of death compared to pregnant women without COVID-19.

1.6%



Estimated chance of maternal death with sotrovimab is 0.2% or 1 in 400. This is 8 times lower than the chance of death for pregnant women who do not have sotrovimab.

0.2%



References

1. Australian National COVID-19 Clinical Evidence Taskforce. Australian guidelines for the clinical care of people with COVID-19. <https://app.magicapp.org/#/guideline/L4Q5An>
2. Villar J, Ariff S, Gunier RB, et al. Maternal and Neonatal Morbidity and Mortality Among Pregnant Women With and Without COVID-19 Infection: The INTERCOVID Multinational Cohort Study. *JAMA Pediatr.* 2021;175(8):817–826. doi:10.1001/jamapediatrics.2021.1050

3. Gupta A, Gonzalez-Rojas Y, Juarez E, Casal MC et al : Early Covid-19 Treatment With SARS-CoV-2 Neutralizing Antibody Sotrovimab. medRxiv 2021/01/01; 2021.05.27.21257096

For information



Sotrovimab Infusion Clinic (10.00am to 6.30pm)

- General information: Sotrovimab@MonashHealth.org
- Bookings, transportation or cancellations: **0448 872 398**

COVID-19 Hotline

- Reporting increased symptoms or side effects (24 hours)
- **1800 675 398**



If you require an interpreter, please call **131 450**

Last reviewed: 18.10.2021	5	Consumer reviewed
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