Preparing for the treatment

A doctor will discuss the risks and benefits of sotrovimab treatment with you (or the child’s parent/legal guardian/other person*/substitute decision-maker) and must obtain consent before it is given. The doctor will need to know about:

• any existing medical conditions
• any previous allergies to medications
• all medications, including over the counter or complementary medications that you (or your child) have been taking
• the possibility that you/the child are pregnant or have plans for a future pregnancy
• if you are breastfeeding
• any recent vaccinations or plans for COVID-19 vaccinations and boosters.

Because sotrovimab is a new medicine, information about how well it works and its safety is still being monitored. It has provisional Therapeutic Goods Administration (TGA) approval. It is important that you understand when and why sotrovimab may be useful. Your doctor will discuss with you about how well it works and how safe it is in your (or your child’s) condition.

How is sotrovimab given to me (or my child)?

Sotrovimab is given once as a single dose. It is given as an infusion via a drip/IV into a vein (usually in the arm). The infusion is given by a nurse, at a hospital or other appropriate healthcare setting. The infusion takes about 30 minutes.

You will be observed/monitored during the infusion and for one hour afterwards to make sure you do not have an allergic reaction.

What are the risks?

All medicines have side effects. Sometimes they are serious, but most of the time they are not. It can also be hard to tell if the side effects are from the sotrovimab or are symptoms of COVID-19.

In the COMET-ICE trial where 526 people had sotrovimab – 5 people reported nausea, 8 people reported diarrhoea, 4 people reported a headache and 9 people had an allergy or reaction to the infusion.1 This information has been sourced from the TGA and the National COVID-19 Clinical Evidence Taskforce, see the links in the section “Where can I find support or more information?”.

Most reactions during the infusion can be treated by slowing down the infusion. A nurse will check on you (or your child) frequently while you (or your child) receive the infusion. Please tell the nurse if you (or your child) feel unwell at any time.

What is sotrovimab and how will it help me (or my child)?

Sotrovimab (so-TROVEE-mab) is a type of medicine called a monoclonal antibody. It has been developed to treat COVID-19. It works by sticking to the spike protein of the virus that causes COVID-19. This stops the virus from attaching to human cells and entering the body. This can help to overcome the infection and stop infected people from getting seriously sick.

Sotrovimab reduces the risk of needing to go to hospital or dying from COVID-19 if used within 5 days of symptoms first appearing. It is approved in Australia to treat mild to moderate COVID-19 in adults and children over 12 years of age (and weighing 40kg or more) who are at risk of becoming severely ill.

Sotrovimab was studied in the COMET-ICE trial.1 This trial helped inform the guidelines of the National COVID-19 Clinical Evidence Taskforce, which were used to create this patient information.

1 Sotrovimab is given via an infusion (also known as a drip or IV). Illustration Copyright © 2019 Nucleus Medical Media, All rights reserved. www.nucleusmedicalmedia.com
Possible side effects of sotrovimab
Tell the doctor or nurse straight away if these symptoms occur:
• mild skin redness or rash (hives)
• diarrhoea.
Reactions while you (or your child) are receiving the sotrovimab infusion symptoms may include:
• fever or chills
• chest pain or pressure
• fast, slow or abnormal heartbeat
• upset stomach
• headache or dizziness
• itchiness and rash.
Severe allergic or infusion reactions may occur during or after the sotrovimab infusion; 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 including itching and hives.
If you start to feel unwell or your symptoms are worse but not serious – call 13 HEALTH (13 43 25 84).
If you have serious symptoms, like difficulty breathing – call 000 and ask for an ambulance.
If the person has already left the healthcare facility, call an ambulance and immediately go to the nearest hospital.

What are the risks of not having sotrovimab?
Sotrovimab is used for the early treatment of COVID-19 in high risk patients with other medical conditions to prevent progression onto severe disease or death and reduce the need for intensive care admission. Your doctor can explain what high-risk means. The decision to receive sotrovimab will depend on your (or your child’s) age, existing medical conditions and if you are vaccinated against COVID-19 or not. Your doctor will discuss your particular health circumstances with you and any related risks.
In the COMET-ICE trial, which looked at the effectiveness of sotrovimab, the group of patients who received the medication had an 85% less chance of needing to go to hospital compared to the group of patients who did not have sotrovimab.1
If you provided consent, you have the right to change your mind at any time prior to the infusion. Please contact the doctor/clinician to discuss.

Are there alternatives?
There are other medications that can be used for COVID-19. Some are intravenous (IV) infusions given through a vein and some are tablets. Your doctor will discuss the best option for you based on your health conditions, availability of the medications and your preferences.

What should I (or my child) expect after treatment?
You will need to stay and be observed by the nurse or doctor for one hour after your infusion to make sure that you don’t have an allergic reaction.
Delayed allergic reactions are rare but can still happen, so it is important that anyone who receives sotrovimab watches carefully for any side effects. Any concerns should be reported to the doctor or nurse immediately.
When your (or your child’s) sotrovimab infusion and observation period is finished, you will be given a letter to confirm where and when you (or your child) had the infusion. The details will also be kept on your (or your child’s) medical record.
Some patients may still develop severe COVID-19 after sotrovimab. It is important that you monitor symptoms and call your local doctor, call 13 HEALTH (13 43 25 84), call 000 or go to your nearest hospital if you start to feel worse due to COVID-19.

When can I (or my child) get vaccinated?
Having sotrovimab won’t affect when your next vaccination is scheduled after you recover from COVID-19.

Is there any impact on fertility, pregnancy and breastfeeding?
Sotrovimab has not been tested on pregnant or breastfeeding women who have COVID-19. The effect of sotrovimab on fertility is unknown. This medication may cross the placenta from mother to baby and the impact of this on the unborn baby is unknown. If you are pregnant, breastfeeding or planning a family, please discuss this with the doctor.

Where can I find support or more information?
• If your symptoms get worse – call 13 HEALTH (13 43 25 84) or 000.

References:

*S formal arrangements, such as parenting/custody orders, adoption, or other formally recognised carer/guardianship arrangements. Refer to the Queensland Health ‘Guide to Informed Decision-making in Health Care’ and local policy and procedures. Complete the source of decision-making authority as applicable.