SA Health

Sotrovimab Drug Monograph

Version 3.0

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Government of South Australia
SA Health

1. Sotrovimab drug monograph

Sotrovimab [1,2,3,4,6,7,9,10,13,23] **ID Approval and patient consent required (verbal or written)** **For the most recent updates on the use of Sotrovimab in patients with COVID-19 visit the Sotrovimab drug guideline available via the NSW Therapeutic Advisory Groupvisit the Sotrovimab drug guideline available via the NSW Therapeutic Advisory Group**	
Drug Class	• Recombinant human IgG1 monoclonal antibody targeting the spike protein of SARS-CoV-2, which is thought to prevent membrane fusion after the virus binds to the human ACE2 receptor.
Indications	Prescribe on advice of Infectious Diseases • There is conflicting in vitro evidence regarding sotrovimab's ability to neutralise the Omicron sublineage BA.2 variant. The clinical significance of this is unclear and evidence is continuing to be reviewed. Recommendations in this guideline will be updated once conclusive evidence is available
Contra-indications	• Hypersensitivity to sotrovimab, or any of the excipients in the product, Chinese hamster ovary cell products or other recombinant human or humanised antibodies. • Exercise caution in patients with a history of anaphylaxis to other medicines. • Children less than 12 years old or weighing < 40kg • For a full list of precautions and considerations for special populations please visit the sotrovimab drug guideline available via the NSW Therapeutic Advisory Group
Precautions	• Renal Impairment: No dose adjustment required • Hepatic Impairment: No dose adjustment required • Pregnancy: No data on the use of sotrovimab in pregnant patients. ○ Use should be considered in pregnant patients, particularly for patients in their second and third trimesters of pregnancy, with additional risk factors for severe COVID-19 infection. • Breastfeeding: Sotrovimab may be used during breastfeeding. The benefits of breastfeeding for both mother and infant are well established. These should be carefully considered against the current unknown but unlikely risks for the use of sotrovimab during breastfeeding. For detailed information, refer to the SA Health Medicines Information sheet "Sotrovimab and Breastfeeding" (also accessed via salus.sa.gov.au)
Drug Interactions	• No formal interaction studies have been conducted with sotrovimab. Sotrovimab is not renally excreted or metabolised by the CYP450 enzymes • For up to date information regarding drug interactions with sotrovimab please check the University of Liverpool COVID-19 resource page • Interaction with COVID-19 vaccination has not been determined. The US Centers for Disease Control and Prevention advises delaying COVID-19 vaccination until 90 days after administration of monoclonal antibodies as part of COVID-19 treatment, to avoid potential interference with the immune response to the COVID-19 vaccination. This advice applies to those who have not received any vaccine dose as well as those who have received the first dose but not the second dose.

Preparation and storage	• Available as a single use vial of 500 mg in 8 mL (62.5 mg/mL) concentrated injection solution for infusion (after diluting). The solution in the vial should be clear and colourless to yellow or brown. • Store refrigerated at 2 - 8^{o}C in original package. Protect from light. Do not freeze.
Dose	• 500mg as a single dose intravenous infusion over 30 minutes
Administration	1. Remove one vial containing 500mg in 8 mL sotrovimab solution from refrigerator at least 15 minutes before preparation of the infusion. 2. Visually inspect vial to ensure no particulate matter is present and there is no damage to the vial (discard if present). 3. Gently swirl the vial several times without creating air bubbles before using - (do NOT shake vigorously). 4. Withdraw 8 mL solution from the sotrovimab vial and inject into a 50 mL or 100mL bag of 0.9% sodium chloride or 5% glucose. 5. Prior to infusion, to mix, gently rock the infusion bag back and forth 3 to 5 times. Do NOT invert the bag. Avoid forming air bubbles. 6. Do not use the same IV line to administer other medications at the same time. 7. Attach an infusion set to the infusion bag using standard bore tubing. Information from the manufacturer states the additional use of a 0.2 micrometre in-line filter is recommended but not essential. 8. Prime the infusion set with sotrovimab infusion and then infuse intravenously over 15 minutes (if using 50 mL bag) or 30 minutes (if using 100 mL bag) (until the bag is empty) via a central or peripheral line. 9. After the sotrovimab infusion is completed, flush the giving set with at least 20 mL of 0.9% sodium chloride or 5% glucose (at the same rate as the sotrovimab infusion).
Monitoring	• Observe the patient for 30 minutes after the infusion is completed in case of infusion reaction or anaphylaxis
Infusion reactions	• Infusion reactions include fever, chills, dizziness, dyspnoea, pruritis and rash. • For mild to moderate infusion reactions, slow or stop the infusion and treat accordingly • Anaphylactic reactions are rare but are a medical emergency. Stop the infusion and commence treatment immediately (see CALHN Anaphylaxis: Management Guidelines CALHN OWI-04038)
Adverse Effects	• It may be difficult to distinguish between adverse effects of sotrovimab and signs and symptoms of COVID-19. • As a new medication, adverse reactions to sotrovimab continue to be investigated. Refer to the product information for a complete list of possible adverse effects. To date reactions include: ▪ Common (>1%): diarrhoea (1%), hypersensitivity reactions (includes rash (2%), infusion-related reaction, bronchospasm). ▪ Rare: anaphylaxis. • Suspected or confirmed adverse reactions should be reported via Safety Learning System and also via the Therapeutic Goods Administrations adverse effects online form: TGA adverse event reporting
Patient information and consent forms	• Sotrovimab patient information leaflets are available here • Sotrovimab patient information leaflets are available via the NSW Therapeutic Advisory Group • Example written and verbal patient consent forms can be found here

2 Definitions/acronyms/abbreviations

BMI	Body Mass Index
COPD	Chronic obstructive pulmonary disease
eGFR	estimated Glomerular Filtration Rate
GI	Gastrointestinal
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
ID	Infectious Diseases
IV	Intravenous
LFTs	Liver function tests
NMS	National Medical Stockpile
NYHA	New York Heart Association

3 Resources

- National COVID-19 Clinical Evidence Taskforce (The Australian Living Guidelines)
- COVID-19 Resources: NSW Therapeutic Advisory Group
- COVID–19 (SARS–COV–2) – Management Guide (CALHN–PRC05409)
- Anaphylaxis: Management Guidelines (CALHN-OWI04038)
- COVID-19: Disease-modifying therapy recommendations for hospitalised adults (CALHN-GDE05778)
- CALHN COVID–19 internet page
- World Health Organisation. Therapeutics and COVID-19: Living Guideline
- Australian Technical Advisory Group on Immunisation (ATAGI)
- Clinical Excellence Commission: Medication Safety Updates
- COVID-19 Treatment: Nirmatrelvir-Ritonavir (Paxlovid®) (IH-CIS05842)
- COVID-19 Resources: Medicines Use in the treatment of COVID-19 – Consent Forms

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5 Document Ownership

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6 Document History

Version	Date approved	Approved by	Amendment notes
3.0	12/04/22	CALHN Drug and Therapeutics Committee South Australian Medicines Advisory Committee	Monograph updated to align with updated COVID-19: Medication management of Mild Illness in the Outpatient Setting Guideline v3.0
2.0	18/02/22	CALHN Drug and Therapeutics Committee COVID-19 Medicines Advisory Group	Add molnupiravir and nirmatrelvir plus ritonavir. Added link on sotrovimab monograph for breastfeeding advice.
1.0	19/01/22	South Australian Medicines Advisory Committee	New guideline to provide a pathway for the medication management of mild COVID-19 illness in the outpatient setting.