

PATIENT MEDICATION INFORMATION

HEALTH CANADA HAS AUTHORIZED THE SALE OF THIS COVID-19 DRUG BASED ON LIMITED CLINICAL TESTING IN HUMANS AND/OR QUALITY INFORMATION.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^P**Sotrovimab for injection**

Read this carefully before you start taking **sotrovimab**. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **sotrovimab**.

What is sotrovimab used for?

Sotrovimab is a medicine being studied to prevent worsening of COVID-19. Sotrovimab may be given if you or your child are 12 years of age or older and weigh at least 40 kg (kilograms) and are not already in the hospital. Sotrovimab is only given to patients at high risk of being hospitalized or dying due to COVID-19, because of their age or medical conditions. Your healthcare professional will decide if you or your child should take sotrovimab.

Sotrovimab is not authorized for use in patients:

- who are in the hospital to treat their COVID-19, OR
- who are given oxygen to help them breathe because of COVID-19.

How does sotrovimab work?

COVID-19 is caused by a coronavirus (SARS-CoV-2). You can get COVID 19 through contact with another person who has the virus.

Sotrovimab is a monoclonal antibody, a type of protein that attaches to the spike protein of the coronavirus (SARS-CoV-2) that causes COVID-19, and prevents the virus from entering and infecting healthy cells within your body. Sotrovimab may help reduce your risk of progressing from mild or moderate COVID-19 to severe infection that requires hospitalization.

What are the ingredients in sotrovimab?

Medicinal ingredients: sotrovimab

Non-medicinal ingredients: L-histidine, L-histidine monohydrochloride, L-methionine, sucrose, polysorbate 80, and water for injection.

Sotrovimab comes in the following dosage forms:

Sotrovimab solution, 500mg/8mL (62.5mg/mL).

Do not use sotrovimab if:

You have had an allergic reaction to sotrovimab or any of the non-medicinal ingredients listed above.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take sotrovimab. Talk about any health conditions or problems you may have, including if you:

- are allergic to any medicines;
- are pregnant or plan to become pregnant;
- are breastfeeding a child or plan to breastfeed;
- have any serious illness;
- are taking any medicines (prescription, over-the-counter, vitamins, or herbal products).

Pregnancy

- Tell your health professional if you are pregnant or if you plan to become pregnant
 - There is not enough information to be sure that sotrovimab is safe for use in pregnancy.
 - Sotrovimab will only be given if the potential benefits of treatment outweigh the potential risks to you and your unborn child.

Breast-feeding

- Tell your health professional if you are breast-feeding or plan to breast-feed
 - It is not yet known whether sotrovimab or the COVID-19 virus pass into human breast milk, or what the effects might be on the baby or milk production.
 - Your health professional will help you decide whether to continue breast-feeding or to start treatment with sotrovimab.
 - You will need to consider the potential benefits of treatment for you, compared with the health benefits and risks of breast-feeding for your baby.

Other warnings you should know about:

A possible side effect of sotrovimab is **allergic reaction**, which can happen during and after infusion with sotrovimab. These reactions may be severe or life threatening. Tell your healthcare professional right away if you get any of the following signs and symptoms of allergic reactions: fever; chills; nausea; headache; shortness of breath; low or high blood pressure; rapid or slow heart rate; chest discomfort or pain; weakness; confusion; feeling tired; wheezing; swelling of your lips, face, or throat; rash including hives; itching; muscle aches; dizziness; and sweating.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take sotrovimab:

- Sotrovimab will be given to you by a qualified healthcare professional intravenously (through a vein) over 60 minutes.
- You will be observed by your healthcare professional during the infusion and for a period of one hour after you receive sotrovimab.

Usual dose:

Sotrovimab is given once. The recommended dose is 500 milligrams (mg).

Overdose:

If you think you, or a person you are caring for, have taken too much sotrovimab, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using sotrovimab?

The side effects of getting any medicine through a vein may include brief pain from inserting the needle, bleeding, bruising of the skin, soreness, swelling, and possible infection at the injection site.

Tell your healthcare professional right away if you get any signs and symptoms of infusion reactions or allergic reactions (see table below).

Some people have had diarrhea when taking sotrovimab.

These are not all the possible side effects you may have when taking sotrovimab. If you experience any side effects not listed here, tell your healthcare professional. Not many people have been given sotrovimab. Serious and unexpected side effects may happen. It is possible that all of the risks of taking sotrovimab are not known at this time.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
<i>Infusion Reaction</i> Fever, chills, nausea or feeling sick, headache, difficulty breathing, chest tightness, fall or increase in blood pressure, swelling of the face, throat irritation, rash with hives, itching or an itchy rash, muscle pain, uneven heart-beat, low oxygen in blood, increased sweating, dizziness or light headedness.		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

It is possible that sotrovimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, sotrovimab may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

If you want more information about sotrovimab:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website <http://www.gsk.ca/>, or by calling 1-800-387-7374.

This leaflet was prepared by GlaxoSmithKline Inc.

Last Revised: January 27, 2023