

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **SARCLISA® SC**

Isatuximab (ee-sah-TUKS-i-mab) **injection**

This patient medication information is written for the person who will be taking **SARCLISA SC**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **SARCLISA SC**, talk to a healthcare professional.

What SARCLISA SC is used for:

SARCLISA SC is used in adults 18 years or older to treat a type of cancer called multiple myeloma. This is a cancer of your plasma cells which are found in your bone marrow.

SARCLISA SC is used together with two other medicines in patients who have received treatments for multiple myeloma before:

- pomalidomide and dexamethasone or
- carfilzomib and dexamethasone.

SARCLISA SC is used together with three other medicines in patients with a newly diagnosed multiple myeloma who cannot receive their own stem cells (autologous bone marrow) transplant:

- bortezomib, lenalidomide, and dexamethasone.

How SARCLISA SC works:

SARCLISA SC is a cancer medicine that contains the active substance isatuximab. It belongs to a group of medicines called “monoclonal antibodies”.

Monoclonal antibodies, such as SARCLISA SC, are proteins that have been designed to recognise and attach themselves to a target substance. In the case of SARCLISA SC, the target is a substance called CD38 that is found on cells of multiple myeloma, a cancer of the bone marrow. By attaching to multiple myeloma cells, the medicine helps the natural defences of your body (immune system) identify and destroy them.

The ingredients in SARCLISA SC are:

Medicinal ingredients: Isatuximab

Non-medicinal ingredients: arginine hydrochloride, histidine, histidine hydrochloride monohydrate, poloxamer 188, sucrose, and water for injection

SARCLISA SC comes in the following dosage forms:

SARCLISA SC is provided as solution for subcutaneous injection. It comes in vials. Each vial of 10 mL contains 1400 mg of isatuximab (140 mg/mL).

Do not use SARCLISA SC if:

- You are allergic to isatuximab or any other ingredients in SARCLISA SC.
- If you are not sure, talk to your doctor or nurse before you receive SARCLISA SC.

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

- Are pregnant, think you might be pregnant, or are planning to have a baby. If you become pregnant while being treated with SARCLISA SC, tell your doctor or nurse immediately. You and your doctor will decide if the benefit of receiving SARCLISA SC is greater than the risk to your baby. Women who are being treated with SARCLISA SC must use effective contraception during treatment and for at least 7 months after treatment.
- Are producing breast milk. You and your doctor will decide if the benefit of breast feeding is greater than the risk to your baby. This is because the medicine may pass into the mother's milk and it is not known if it will affect the baby.
- Have had shingles (herpes zoster).

Other warnings you should know about:

Allergic reactions (called systemic administration reactions)

Tell your doctor or nurse immediately if you have signs of allergic reactions during or after the injection of SARCLISA SC.

Severe symptoms of allergic reactions to the injection include:

- high blood pressure (hypertension)
- feeling short of breath (dyspnoea)

The most common signs of allergic reactions to the injection include:

- fever, chills
- feeling short of breath (dyspnoea)
- faster heart rate (sinus tachycardia)

Before your first SARCLISA SC subcutaneous injection, you will receive other medicines to reduce the symptoms of the allergic reactions at least for the first injections. It makes them less frequent and severe.

Allergic reactions can happen during or after the SARCLISA SC injection. In most cases, these reactions were not serious. They were reversible and resolved at the most within 3 days. If you get an allergic reaction, your doctor or nurse may give you additional medicines to treat your symptoms and prevent complications. They may also adjust your treatment, as needed.

Blood Transfusion

If you need a blood transfusion, you will have a blood test first to match your blood type. SARCLISA SC can affect the results of this blood test for at least 6 months after your last dose. Tell the person doing the test that you are using SARCLISA SC. Your doctor should do blood tests to match your blood type before you start treatment with SARCLISA SC.

Decreased Number of White Blood Cells

Tell your doctor or nurse immediately if you develop fever, as it may be a sign of infection. SARCLISA SC can decrease the number of your white blood cells, which are important in fighting infections. Your doctor will monitor for your white blood cells during SARCLISA SC treatment. Your doctor may prescribe an antibiotic or antiviral medicine (for example, for herpes zoster) to help prevent infection, or a medicine to help increase your white blood cell counts during treatment with SARCLISA SC.

Infections

SARCLISA SC when combined with other drugs including pomalidomide and dexamethasone or carfilzomib and dexamethasone or bortezomib, lenalidomide, and dexamethasone may increase the risk of infections. These infections can be severe or life-threatening. Tell your doctor right away if you have a fever or chill, feel very tired, have a cough or have flu-like symptoms.

Children and Adolescents

SARCLISA SC should not be used in children and adolescents under the age of 18. This is because the effectiveness of SARCLISA SC has not been established in paediatric patients.

Driving and Using Machines

Fatigue and dizziness have been reported by patients taking SARCLISA SC. If you feel tired or dizzy, do not drive or use machines until you feel better. SARCLISA SC is used with other medicines that may affect your ability to drive or use machines. Please look at the package leaflet from the other medicines you take with SARCLISA SC.

Heart Problems

SARCLISA SC in combination with carfilzomib and dexamethasone can cause heart problems and/or make your heart beat faster. Tell your doctor or nurse before using SARCLISA SC in combination with carfilzomib and dexamethasone if you have any heart problems, or if you have ever taken a medicine for your heart. During treatment, if you feel your heart racing, an irregular heartbeat, dizziness, shortness of breath, chest pain, cough or leg swelling, contact your doctor or nurse immediately.

New Cancers

New cancers have happened in patients during treatment with SARCLISA SC. It is not clear if SARCLISA SC causes new cancers. Your doctor will monitor you for new cancers.

Tumour lysis syndrome

A fast breakdown of cancer cells (called tumour lysis syndrome) was reported with SARCLISA intravenous formulation but has not been reported with the subcutaneous administration of SARCLISA SC. In case it occurs, symptoms may include irregular heartbeat, seizures (fits), confusion, muscle cramps, or decrease in urine output. Contact your doctor immediately if you experience any of these symptoms.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. Tell your doctor or nurse before SARCLISA SC treatment if you have ever taken a medicine for your heart.

How to take SARCLISA SC:

- Your doctor or nurse will prepare and inject your dose of SARCLISA SC under your skin (subcutaneous injection).
- Injections will be given only into the stomach area (abdomen) where the skin is not tender, red, bruised, with scars or excessively hairy.
- Your doctor or nurse will either use a special injector (the CirCLIQ On-Body Delivery System) or a syringe to inject SARCLISA SC. The injection will usually last less than 20 minutes with the On-body Delivery System and 6 minutes with the syringe.
- Your doctor or nurse will make sure to rotate the injection site for each SARCLISA SC injection
- Your doctor or nurse will use different places for injection for the other medicines that need to be injected.

Usual dose:

The recommended dose of SARCLISA SC is 1,400 mg.

When SARCLISA SC is used with two other medicines, either pomalidomide and dexamethasone or carfilzomib and dexamethasone, each treatment cycle lasts 28 days (4 weeks):

- In cycle 1: SARCLISA SC is given once a week on days 1, 8, 15 and 22.
- In cycle 2 and beyond: SARCLISA SC is given every 2 weeks - on days 1 and 15.

When SARCLISA SC is used with three other medicines, bortezomib, lenalidomide, and dexamethasone, each treatment cycle lasts 42 days (6 weeks) from cycle 1 to 4 and 28 days (4 weeks) from cycle 5 and onwards.

- In cycle 1: SARCLISA SC is administered on days 1, 8, 15, 22, and 29.
- From cycle 2 to 4: SARCLISA SC is administered every 2 weeks - on days 1, 15, and 29.
- From cycle 5 to 17: SARCLISA SC is administered every 2 weeks - on days 1 and 15.
- From cycle 18 and onwards: SARCLISA SC is administered every 4 weeks - on day 1.

Your doctor will continue to treat you with SARCLISA SC as long as you benefit from it and tolerate the potential side effects.

Medicines given before SARCLISA SC

You will be given the following medicines before administration of SARCLISA SC. This is to help reduce the symptoms of the allergic reactions to SARCLISA SC injection:

- Medicine to reduce allergic reactions (anti-histamines and/or montelukast)
- Medicine to reduce inflammation (corticosteroids)
- Medicine to reduce pain and fever (such as paracetamol)

Overdose:

SARCLISA SC will be given to you by your doctor or nurse. In the unlikely event that you are given too much (an overdose), your doctor will monitor you for side effects.

If you think you, or a person you are caring for, have taken too much SARCLISA SC, contact a healthcare professional, hospital emergency department, or regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

It is very important that you go to all your appointments to make sure your treatment works. If you miss any appointments, call your doctor or nurse as soon as possible to reschedule your appointment. Your doctor or nurse will decide how your treatment should be continued.

Possible side effects from using SARCLISA SC:

These are not all the possible side effects you may have when taking SARCLISA SC. If you experience any side effects not listed here, tell your healthcare professional.

- tingling or numbness of the arms and legs (peripheral sensory neuropathy)

- constipation
- diarrhoea
- infection of the upper airways (such as nose, sinuses or throat)
- tiredness
- local skin reactions at or near the injection site including redness of the skin, itching, swelling, pain (Injection site reactions)
- difficulty sleeping
- polyneuropathy including but not limited to sensitivity, burning sensation of the skin, numbness, tingling, weakness, and/or loss of sensation in the legs and arms
- red skin rash (erythema)
- swelling of the ankles, feet or fingers (peripheral oedema)
- back pain
- nausea
- high blood pressure (hypertension)
- muscle spasm
- weight loss
- bronchitis
- covid-19
- flu
- vomiting
- fever

Serious side effects and what to do about them

Frequency/Side effect/Symptom	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON (1 in 10 people)			
Low number of blood cells such as: • Platelets (thrombocytopenia) (symptoms like unusual bruising or bleeding) • White blood cells (neutropenia or lymphopenia) • Red blood cells (anemia) (symptoms like fatigue, loss of energy, weakness, shortness of breath)		✓	
Lung infection such as pneumonia, bronchitis, lower respiratory tract infections Symptoms can include congestion, cough (may produce phlegm), body ache, tiredness, wheezing, shortness of breath, chest pain when breathing or cough, fever, sweating and chill, and confusion or change of mental awareness (mostly in older patients).		✓	
Second primary malignancies		✓	

Frequency/Side effect/Symptom	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Other cancers, most commonly cancers of the skin (e.g., squamous cell carcinomas) with some new solid tumours and blood cancers. The skin cancers may appear as a firm, red bumps, or flat sores with rough scaly patches on the skin, lips or inside the mouth			
COMMON (less than 1 in 10, but more than 1 in 100)			
Herpes viral infection The infection can present as a cold sore. Symptoms can include a sore on the lip or in the mouth, painful blisters on the skin, fever, feeling tired, body ache, rash, or red spots and blisters over the entire body. The infection can also present as herpes zoster (shingles), a viral herpes infection affecting the nerves whose symptoms can include painful rashes of small blisters along a nerve path, arising in one or more affected areas.	✓		
Allergic reactions to SARCLISA SC injection (systemic administration reactions) Symptoms can include high blood pressure, shortness of breath, fever, chills and faster heart rate.		✓	
Irregular or rapid heartbeat Symptoms can include heart racing, irregular heartbeat, dizziness, shortness of breath and chest pain.		✓	
Heart problems, which may present as difficulty breathing, cough, or leg swelling when SARCLISA SC is given with carfilzomib and dexamethasone		✓	

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.

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 (canada.ca/drug-device-reporting) 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.

Storage:

SARCLISA SC should not be used after the expiry date which is stated on the label and carton. Once the vial has been taken out of the refrigerator, it must not be returned to the refrigerator.

SARCLISA SC should be stored in a refrigerator (2°C to 8°C) until 20 minutes prior to use.

Store in the original package in order to protect from light. Do not freeze. Do not shake.

Keep out of reach and sight of children.

If you want more information about SARCLISA:

- 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>); sanofi-aventis Canada website <https://www.sanofi.com/en/canada/>, or by calling 1-800-265-7927.

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