

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr SARCLISA[®]

Isatuximab for injection

concentrate for solution for infusion

Read this carefully before you start taking **Sarclisa (sar-KLEE-sah)** and each time you get a refill. 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 **Sarclisa**.

What is Sarclisa used for?

Sarclisa 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 is used to treat multiple myeloma in patients who have received treatments for multiple myeloma before.

Sarclisa is used together with two other combinations of medicines

- pomalidomide and dexamethasone or;
- carfilzomib and dexamethasone

How does Sarclisa work?

Sarclisa is a cancer medicine that contains the active substance isatuximab (ee-sah-TUKS-i-mab). It belongs to a group of medicines called “monoclonal antibodies”.

Monoclonal antibodies, such as Sarclisa, are proteins that have been designed to recognise and attach themselves to a target substance. In the case of Sarclisa, 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.

What are the ingredients in Sarclisa?

Medicinal ingredients: Isatuximab

Non-medicinal ingredients: Histidine, Histidine hydrochloride monohydrate, Polysorbate 80, Sucrose, Water for injection

Sarclisa comes in the following dosage forms:

Sarclisa is provided as a concentrate that must be diluted and is then administered by intravenous infusion. It comes in vials. Each vial of 5 mL concentrate contains 100 mg of isatuximab (concentration of 20 mg/mL). Each vial of 25 mL concentrate contains 500 mg of isatuximab (concentration of 20 mg/mL).

Do not use Sarclisa if:

- You are allergic to isatuximab or any other ingredients in Sarclisa.

If you are not sure, talk to your doctor or nurse before you receive Sarclisa.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Sarclisa. 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, tell your doctor or nurse immediately. You and your doctor will decide if the benefit of receiving Sarclisa is greater than the risk to your baby. Women who are being treated with Sarclisa must use effective contraception during treatment and for at least 5 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.

Other warnings you should know about:

Infusion-Related Reactions

Infusion-related reactions can happen during Sarclisa infusion or after the infusion and may be serious. Tell your doctor or nurse immediately if you feel unwell during or after infusion of Sarclisa. These symptoms may include:

- Feeling short of breath
- Cough
- Stuffy or runny nose
- Chills
- Nausea
- Vomiting

Severe symptoms of infusion reaction are less common, including:

- High blood pressure (hypertension)
- Low oxygen level in the blood (hypoxia)
- Low blood pressure (hypotension)
- Fast heartbeat (tachycardia)
- High level of blood sugar (hyperglycemia)
- Swollen face, lips, mouth, tongue or throat

If you have an infusion-related reaction, you may need other medicines to treat your symptoms, or the infusion may need to be slowed down or stopped. When these reactions go away or get better, the infusion can be started again.

Blood Transfusion

If you need a blood transfusion, you will have a blood test first to match your blood type. Sarclisa can affect the results of this blood test. Tell the person doing the test that you are using Sarclisa. Your doctor should do blood tests to match your blood type before you start treatment with Sarclisa.

Decreased Number of White Blood Cells

Sarclisa 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 treatment. You may receive other medications to treat low white blood cells.

Infections

Sarclisa when combined with other drugs including pomalidomide and dexamethasone or carfilzomib 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 is not approved for use in children and adolescents under the age of 18.

Driving and Using Machines

Sarclisa is not expected to affect your ability to drive or use machines. However, fatigue and dizziness have been reported by patients taking Sarclisa. If you experience side effects of this medicine, do not drive or use machines before discussing with your doctor, pharmacist or nurse.

Heart Problems

Sarclisa can cause heart problems and/or make your heart beat faster. Tell your doctor or nurse if you have any heart problems, or if you have ever taken a medicine for your heart. During Sarclisa treatment, if you feel heart racing, 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. It is not clear if Sarclisa has caused the new cancers. Your doctor will monitor you for new cancers.

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 treatment if you have ever taken a medicine for your heart.

How to take Sarclisa:

- Your doctor or nurse will give you Sarclisa in your vein (intravenously) as a drip infusion.

Usual dose:

Your doctor will determine your dose of Sarclisa. This will depend on your body weight. The recommended dose is 10 mg of Sarclisa per kilogram of your body weight.

Sarclisa is used in treatment cycles of 28 days (4 weeks) together with either pomalidomide and dexamethasone or carfilzomib and dexamethasone:

- In Cycle 1: Sarclisa is administered weekly on days 1, 8, 15 and 22
- In Cycle 2 and beyond: Sarclisa is administered every 2 weeks on day 1 and 15

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

Medicines given before an infusion of Sarclisa

You must receive the following medicines before infusion of Sarclisa to help reduce possible infusion-

related reactions:

- Medicine to reduce allergic reactions (anti-histamine)
- Medicine to reduce inflammation (corticosteroid)
- Medicine to reduce pain and fever

Overdose:

Sarclisa 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, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no 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.

What are possible side effects from using Sarclisa?

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

- Headache
- Dizziness
- Feeling tired
- Decreased appetite
- Hiccups
- Runny or stuffy nose, sneezing, coughing, sore or scratchy throat (infection of the upper airways, such as nose, sinuses or throat)
- Nausea, vomiting
- Diarrhea
- Abdominal pain or discomfort
- Heartburn
- Swelling of the hands or legs
- Muscle, bone or joint pain
- Decreased body weight
- Feeling anxious
- Blurred vision
- High blood sugar
- Loss of bladder control (urinary incontinence)
- High blood pressure (hypertension)
- Hot flushes

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	
VERY COMMON (1 in 10 people)			
Infusion-related reactions Symptoms can include one or more of the following: feeling short of breath, cough, stuffy or runny nose, chills, nausea, high blood pressure (hypertension), fast heartbeat, low blood pressure, swollen face, lips, mouth, tongue or throat.			✓
Low number of blood cells such as: <ul style="list-style-type: none"> • 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).		✓	
Shortness of breath		✓	
COMMON (less than 1 in 10, but more than 1 in 100)			
Herpes viral infection The infection can present as cold sore, shingles, or chickenpox. The symptoms can include sore on the lip or in the mouth, painful blisters on the skin, fever, feeling tired, body ache, rash, and red spots and blisters over the entire body.	✓		
Irregular or rapid heartbeat Symptoms can include heart racing, irregular heartbeat, dizziness, shortness of breath and chest pain.		✓	
Squamous cell carcinoma of the skin It may appear as a firm, red nodule, or a flat sore with a rough scaly patch on		✓	

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	
the skin, lips or inside the mouth.			
Pulmonary embolism. Symptoms can include sudden feeling short of breath, sharp chest pain, cough, heart racing, sweating, feeling anxious and fainting.			✓
Heart problems, which may present as difficulty breathing, cough, or leg swelling when Sarclisa is given with carfilzomib and dexamethasone		✓	
RARE (may affect up to 1 in 100 people)			
Serious allergic reaction (anaphylactic reaction), which may include rash, itching, difficulty breathing, shortness of breath, swelling of the face, mouth, throat, or tongue, cold, clammy skin, palpitations, dizziness, weakness or fainting			✓

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.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • 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. <p><i>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.</i></p>
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Storage:

Sarclisa should not be used after the expiry date which is stated on the label and carton.

Sarclisa should be stored in a refrigerator (2°C to 8°C), in its original package to protect from light.

Do not freeze.

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 www.sanofi.ca, or by calling 1-800-265-7927.

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