

SARCLISA[®]

isatuximab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Sarclisa. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Sarclisa against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Sarclisa is used for

Sarclisa is an anti-cancer medicine that contains the active substance isatuximab. It is a type of medicine called “monoclonal antibodies”. Monoclonal antibodies can specifically target cancer cells so that your immune system can attack them.

Sarclisa is used to treat “multiple myeloma”. This is a type of cancer of your bone marrow.

Sarclisa is used together with two other medicines called pomalidomide and dexamethasone. This treatment is for patients who have received at least 2 treatments for multiple myeloma before.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

Sarclisa is not expected to affect your ability to drive or use machines. However, if you experience side effects of this medicine, do not drive or use machines before discussing with your doctor.

Before you are given Sarclisa

When you must not take it

Do not take Sarclisa if you have an allergy to:

- The active ingredient isatuximab or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Use of Sarclisa is not recommended during pregnancy.

It may affect your developing baby if you take it during pregnancy.

Women who are using Sarclisa and are able to become pregnant must use an effective method of contraception during treatment and for 5 months after the last dose of Sarclisa.

Do not breast-feed if you are taking this medicine.

The active ingredient in Sarclisa may pass into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- **Decreased number of white blood cells:** Sarclisa can decrease the number of your white blood cells, which are important in fighting infections. Tell your doctor or nurse straight away if you develop fever.

If you have not told your doctor about any of the above, tell him/her before you start taking Sarclisa.

Before starting using Sarclisa, you must also read the package leaflet of all medicines to be taken together with Sarclisa for information related to these medicines.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Sarclisa may interfere with each other.

Your doctor has more information on medicines to be careful with or avoid while taking this medicine.

How Sarclisa is given

How much Sarclisa is given

The amount of Sarclisa you will be given will be calculated based on your body weight. The recommended dose is 10 mg of Sarclisa per kilogram of your body weight.

How to take it

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

When to take it

Sarclisa is used in treatment cycles of 28 days (4 weeks) together with pomalidomide 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

Medicines given before infusion of Sarclisa

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

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

How long to take it

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

Do not stop your treatment with Sarclisa unless you have discussed that with your doctor.

If you miss a 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.

If you take too much (overdose)

Sarclisa will be given to you by your doctor or nurse. If you are accidentally given too much (an overdose), your doctor will treat and monitor your side effects.

While you are using Sarclisa

Things you must do

Tell any other doctors, dentists, and pharmacists who treat you that you are having Sarclisa.

If you are going to have surgery, tell the surgeon or anaesthetist that you are having Sarclisa.

If you are pregnant or planning to become pregnant, talk to your doctor about using SARCLISA.

If you are about to have any blood tests, tell your doctor that you are given Sarclisa.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some blood and other tests from time to time to check your response to the treatment and to prevent unwanted side effects.

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.

Infusion-related reactions

Infusion reactions can happen during Sarclisa infusion or after the infusion, the day of the infusion. **Tell your doctor or nurse straight away if you experience symptoms listed in the Side Effects section during or after the infusion of Sarclisa.**

The hospital staff will monitor your condition closely during treatment. In case of infusion reactions, your doctor or nurse may decide to give you additional medicines to treat your symptoms and prevent complications, or temporarily stop the infusion, slow it down, or completely stop it.

Things to be careful of

Be careful driving or operating machinery until you know how Sarclisa affects you.

Sarclisa is not expected to affect your ability to drive or use machines. However, Sarclisa may cause dizziness and tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Like all medicines, Sarclisa can cause side effects, although not everybody gets them.

Your doctor will discuss the side effects of Sarclisa with you and will explain the potential risks and benefits of your treatment with Sarclisa.

The hospital staff will monitor your condition closely during treatment.

Tell them immediately if you do not feel well while you are given Sarclisa.

Infusion reactions have been observed with the use of Sarclisa. Tell your doctor or nurse straight away if you experience symptoms of infusion reaction during the infusion of Sarclisa.

The most common symptoms of infusion reaction that you may experience include the following:

- feeling short of breath
- cough
- chills
- nausea

The most common severe symptoms of infusion reaction include the following:

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

Other symptoms may occur as well. Your doctor or nurse may decide to interrupt, slow down, or completely stop the Sarclisa infusion, and may decide to give you additional medicines to treat your symptoms and prevent complications.

Below are other side effects that you may experience:

Very common (may affect more than 1 in 10 people):

- decrease in the number of red blood cells (anaemia)
- decrease in the number of types of white blood cells (neutrophils or lymphocytes which are important in fighting infection)
- decrease in the number of blood platelets (thrombocytopenia). Tell your doctor or nurse if you have any unusual bruising or bleeding.
- infection of the lungs (pneumonia)
- infection of the airways (such as nose, sinuses or throat)
- diarrhoea
- bronchitis
- feeling short of breath
- nausea
- fever associated with a severe decrease in the number of some white blood cells (febrile neutropenia)
- vomiting

Do not be alarmed by the above lists of side effects. You may not experience any of them.

Ask your doctor or nurse to answer any questions you may have.

After using Sarclisa

Storage

Sarclisa will be stored at the hospital or clinic in a refrigerator at 2°C-8 °C.

Store in the original package in order to protect from light.

Keep this medicine out of the sight and reach of children.

Disposal

Sarclisa is for single use in one patient only. Any residue will need to be discarded.

Your doctor or nurse will dispose Sarclisa that is no longer used.

Product description

What it looks like

Sarclisa is a colourless to slightly yellow liquid for infusion available in two different strengths:

- 100mg/5mL available in pack sizes of 1 or 3 colourless clear glass vials
- 500mg/25mL available in a pack size of 1 colourless clear glass vial

Not all pack sizes may be marketed.

Ingredients

1 vial of Sarclisa contains 100mg or 500mg isatuximab as the active ingredient.

Other ingredients:

- Sucrose
- Histidine hydrochloride monohydrate
- Histidine
- Polysorbate 80

- Water for injections

Manufacturer/Distributor/Supplier

Sarclisa is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email:

medinfo.australia@sanofi.com

Sarclisa is distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

Freecall: 0800 283 684

Email:

medinfo.australia@sanofi.com

Sarclisa 100mg/5mL vial

AUST R 319086

Sarclisa 500mg/25mL vial

AUST R 319085

This leaflet was prepared in May 2024.

sarc-ccdsv1-cmiv1-23may24