Package leaflet: Information for the patient

SARCLISA® 20 mg/mL concentrate for solution for infusion

isatuximab

The name of your medicine is SARCLISA 20 mg/mL concentrate for solution for infusion but will be referred to as Sarclisa or SARCLISA throughout this leaflet.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sarclisa is and what it is used for

What Sarclisa is
Sarclisa 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, 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 is Sarclisa used for
Sarclisa is used to treat multiple myeloma.

It is used together with two other medicines in patients who have received treatments for multiple myeloma before:
- pomalidomide and dexamethasone or
- carfilzomib and dexamethasone.

It is used together with three other medicines in patients with newly diagnosed multiple myeloma:
- bortezomib, lenalidomide and dexamethasone.

If you have any questions on how Sarclisa works or about your treatment with Sarclisa, ask your doctor.

2. What you need to know before you use Sarclisa

You must not be given Sarclisa if:
- you are allergic to isatuximab or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or nurse before using Sarclisa and follow all instructions carefully.

Infusion reactions
Tell your doctor or nurse immediately if you have signs of infusion reactions during or after the infusion of Sarclisa - see in section 4 "Possible side effects" for the list of signs of ‘Infusion reactions’.
- Before starting a Sarclisa infusion, you may be given medicines to reduce infusion reactions (see section 3 "How Sarclisa is given").
- Infusion reactions can happen during the Sarclisa infusion or after the infusion and may be serious. These reactions are reversible. The hospital staff will monitor you closely during treatment.

If you get an infusion reaction, your doctor or nurse may give you additional medicines to treat your symptoms and prevent complications. They may also temporarily stop, slow down, or completely stop the Sarclisa infusion.

Fever and low number of white blood cells
Tell your doctor or nurse immediately if you develop fever, as it may be a sign of infection. Sarclisa can lower the number of white blood cells - which are important for fighting infections.

Your doctor or nurse will check your blood cell counts during treatment with Sarclisa. Your doctor may prescribe an antibiotic or antiviral medicine (for example, for herpes zoster [shingles]) to help prevent infection, or a medicine to help increase your white blood cell counts during treatment with Sarclisa.

Heart problems
Talk to your doctor or nurse before using Sarclisa in combination with carfilzomib and dexamethasone if you have heart problems, or if you have ever taken a medicine for your heart. Contact your doctor or nurse immediately if you experience any difficulty breathing, cough, or leg swelling.

Risk of new cancers
New cancers have occurred in patients during treatment with Sarclisa when given with pomalidomide and dexamethasone, or with carfilzomib and dexamethasone, or with bortezomib, lenalidomide and dexamethasone. Your doctor or nurse will monitor you for new cancers during treatment.

Tumour lysis syndrome
A fast breakdown of cancer cells (tumour lysis syndrome) may occur. 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.

Blood transfusion
If you need a blood transfusion, you will have a blood test first to match your blood type.

Tell the person doing the blood test that you are being treated with Sarclisa. This is because it may affect the results of this blood test for at least 6 months after your final dose of Sarclisa.

Children and adolescents
Sarclisa is not recommended for use in children and adolescents aged under 18 years. This is because the effectiveness of Sarclisa has not been established in paediatric patients.

Other medicines and Sarclisa
Tell your doctor, pharmacist or nurse if you are taking, have recently taken, or might take any other medicines. This includes medicines you can get without a prescription, and herbal medicines.

Tell your doctor or nurse before having Sarclisa if you have ever taken a medicine for your heart.

Sarclisa is used together with two or three other medicines when treating multiple myeloma:
- pomalidomide and dexamethasone or
- carfilzomib and dexamethasone or
- bortezomib, lenalidomide and dexamethasone.

For information on the other medicines used with Sarclisa, see their package leaflets.

Pregnancy
Ask your doctor, pharmacist or nurse for advice before using Sarclisa. Use of Sarclisa is not recommended during pregnancy. If you are pregnant or planning to become pregnant, talk to your doctor about using Sarclisa.

For information on pregnancy and other medicines that are taken with Sarclisa, please look at the package leaflet for these other medicines.

Breast-feeding
Ask your doctor, pharmacist or nurse for advice before using Sarclisa.
- This is because Sarclisa may pass into breast milk. It is not known how it could affect the baby.
- You and your doctor will decide if the benefit of breast-feeding is greater than the risk to your baby.

Contraception
Women who are using Sarclisa and are able to become pregnant must use an effective method of contraception. Talk to your doctor about the method of contraception that you must use during this time. Use contraception during treatment – and for 5 months after the last dose of Sarclisa.

Driving and using machines
Sarclisa is unlikely to affect your ability to drive or use machines. However, Sarclisa 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.

Sarclisa contains polysorbate 80
This medicine contains 0.2 mg of polysorbate 80 in each mL of isatuximab concentrate for solution for infusion, which is equivalent to 0.1 mg/kg of body weight. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How Sarclisa is given

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

How Sarclisa is given
Your doctor or nurse will give you Sarclisa as a drip into a vein (intravenous infusion).

How often Sarclisa is given
When Sarclisa is used with two other medicines, either pomalidomide and dexamethasone or carfilzomib and dexamethasone, the treatment cycles last 28 days (4 weeks).
- In cycle 1: Sarclisa is given once a week on days 1, 8, 15 and 22
- In cycle 2 and beyond: Sarclisa is given every 2 weeks – on days 1 and 15

When Sarclisa is used with three other medicines, bortezomib, lenalidomide and dexamethasone:
– For patients unsuitable for autologous bone marrow (their own stem cells) transplant:
The treatment cycles last 42 days (6 weeks) from cycle 1 to 4 and lasts 28 days (4 weeks) from cycle 5 and onwards.
- In cycle 1: Sarclisa is given on days 1, 8, 15, 22 and 29
- From cycle 2 to 4: Sarclisa is given every 2 weeks – on days 1, 15 and 29
- From cycle 5 to 17: Sarclisa is given every 2 weeks – on days 1 and 15
- From cycle 18 and onwards: Sarclisa is given every 4 weeks – on day 1

– For patients suitable for autologous bone marrow (their own stem cells) transplant:
The treatment cycles last 42 days (6 weeks) from cycle 1 to 3.
- In cycle 1: Sarclisa is given on days 1, 8, 15, 22 and 29
- From cycle 2 to 3: Sarclisa is given every 2 weeks - on days 1, 15 and 29

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

Medicines given before Sarclisa
You will be given the following medicines before infusion of Sarclisa. This is to help reduce your chances of getting infusion reactions:
- medicines to reduce allergic reactions (antihistamine)
- medicines to reduce inflammation (corticosteroids)
- medicine to reduce pain and fever

If you miss a dose of Sarclisa
It is very important that you go to all your appointments to make sure you receive your treatment at the right time for it to work properly. If you miss any appointments, call your doctor or nurse as soon as possible to reschedule the appointment.

Your doctor or nurse will decide how your treatment should be continued.

If you are given more Sarclisa than you should
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.

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

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

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

The hospital staff will monitor your condition closely during treatment. Tell them immediately if you notice any of the effects below.

Infusion reactions - Very common (may affect more than 1 in 10 people):
Tell your doctor or nurse immediately if you feel unwell during or after the infusion of Sarclisa.

Severe signs of infusion reaction include:
- high blood pressure (hypertension)
- feeling short of breath
- serious allergic reaction (anaphylactic reaction affecting up to 1 in 100 people) with breathing difficulty and swelling of the face, mouth, throat, lips or tongue

The most common signs of infusion reaction include:
- feeling short of breath
- cough
- chills
- nausea

You may also have other side effects during the infusion. Your doctor or nurse may decide to temporarily stop, slow down, or completely stop the Sarclisa infusion. They may also give you additional medicines to treat your symptoms and prevent complications.

Tell your doctor or nurse immediately if you feel unwell during or after the infusion of Sarclisa.

Other side effects
Talk to your doctor, pharmacist or nurse immediately if you have any of the side effects listed below:

Very common (may affect more than 1 in 10 people):
- lower number of some white blood cells (neutrophils) which are important in fighting infection
- lower 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
- vomiting
- high blood pressure (hypertension)
- cough
- tiredness (fatigue)
- decreased appetite
- Covid-19
- clouding of your eye (cataract)

Common (may affect up to 1 in 10 people):
- heart problems, which may present as difficulty breathing, cough, or leg swelling when Sarclisa is given with carfilzomib and dexamethasone
- fever with a severe decrease in some white blood cells (febrile neutropenia) (see section 2 "What you need to know before you use Sarclisa" for further details)
- lower number of red blood cells (anaemia)
- weight loss
- irregular heartbeat (atrial fibrillation)
- herpes zoster (shingles)
- lower number of some white blood cells (lymphocytes) which are important in fighting infection

If any of the above apply to you, or you are not sure, talk to your doctor, pharmacist or nurse immediately.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Sarclisa

Sarclisa will be stored at the hospital or clinic.

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

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

Store in a refrigerator (2 °C – 8 °C). Do not freeze.
Store in the original package in order to protect from light.

If this medicine becomes discoloured or shows any other signs of deterioration, please contact your pharmacist who will advise you on what to do.

Medicines should not be disposed of via wastewater. Your doctor, pharmacist or nurse will throw away any medicines that are no longer being used. These measures will help protect the environment.

6. Contents of the pack and other information

What Sarclisa contains

- The active substance of Sarclisa is isatuximab.
- One mL of concentrate contains 20 mg of isatuximab.
- Each vial of concentrate contains either 100 mg of isatuximab in 5 mL of concentrate or 500 mg of isatuximab in 25 mL of concentrate.
- The other ingredients (excipients) are sucrose, histidine hydrochloride monohydrate, histidine, polysorbate 80 (E433), and water for injections (see SmPC sections 2 and 4.4).

What Sarclisa looks like and contents of the pack
Sarclisa is a concentrate for solution for infusion.
It is a colourless to slightly yellow liquid, essentially free of visible particles.

Pack size:
100 mg of isatuximab in 5 mL of concentrate (100 mg/5 mL): Each carton contains 1 vial.
500 mg of isatuximab in 25 mL of concentrate (500 mg/25 mL): Each carton contains 1 vial.
Not all pack sizes may be marketed.

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor, nurse or pharmacist.

SARCLISA 20 mg/mL concentrate for solution for infusion
PL 45985/1128

POM

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Blind or partially sighted?
Is this leaflet hard to see or read?
Call +45 63 95 27 00
to obtain the leaflet in a format suitable for you.

The following information is intended for healthcare professionals only:
SARCLISA vials are for single-use only. The infusion solution must be prepared under aseptic conditions, and administered by a healthcare professional in an environment where resuscitation facilities are available.

Preparation and administration of SARCLISA

- Calculate the dose (mg) of required SARCLISA concentrate, and determine the number of vials needed for the 10 mg/kg dose, based on the patient weight. More than one vial may be needed.
- Visually check the SARCLISA concentrate before dilution to ensure it does not contain any particles and is not discoloured.
- Remove the volume of diluent equal to the required volume of SARCLISA concentrate from a 250 mL of sodium chloride 9 mg/mL (0.9%) solution for injection or glucose 5% solution diluent bag.
- Withdraw the appropriate volume of SARCLISA concentrate from the SARCLISA vial and dilute it in the 250 mL infusion bag with sodium chloride 9 mg/mL (0.9%) solution for injection or glucose 5% solution.
- The infusion bag must be made of polyolefins (PO), polyethylene (PE), polypropylene (PP), polyvinyl chloride (PVC) with di (2-ethylhexyl) phthalate (DEHP) or ethyl vinyl acetate (EVA).
- Gently invert the bag to homogenize the diluted solution. Do not shake.
- Administer the infusion solution intravenously using an intravenous tubing infusion set (in PE, PVC with or without DEHP, polybutadiene (PBD) or polyurethane (PU)) with a 0.22 micron in-line filter (polyethersulfone (PES), polysulfone or nylon).
- Administer the infusion solution for a period of time that will depend on the infusion rate (see SmPC section 4.2 "Posology and method of administration").
- Use the prepared SARCLISA infusion solution immediately. If not used immediately, in-use storage times and conditions prior use are the responsibility of the user and should normally not be longer than 24 hours at 2 °C – 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.
- No protection from light is required for the prepared infusion bag in a standard artificial light environment.
- Do not infuse SARCLISA solution concomitantly in the same intravenous line with other agents.
- Discard all unused portions of solution. All materials that have been utilised for dilution and administration should be disposed of according to standard procedures.