

**Package leaflet:**  
**Information for the patient**

## Sarclisa® 1400 mg solution for injection

isatuximab

**sanofi**

### Is this leaflet hard to see or read? Phone 0800 035 2525 for help

**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.
- It is important that you keep the Patient Card with you during treatment and for at least 6 months after the treatment has ended.
- 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 “Possible side effects”).

**What is in this leaflet**

- What Sarclisa 1400 mg solution for injection is and what it is used for
- What you need to know before you are given Sarclisa 1400 mg solution for injection
- How Sarclisa 1400 mg solution for injection is given
- Possible side effects
- How to store Sarclisa 1400 mg solution for injection
- Contents of the pack and other information

### 1. What Sarclisa 1400 mg solution for injection is and what it is used for

**What Sarclisa 1400 mg solution for injection** 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.



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In the case of Sarclisa, the target is a substance called CD38 that is found on plasma cells in patients with multiple myeloma, a cancer of the bone marrow. By attaching to plasma cells, the medicine helps the natural defences of your body (immune system) to identify and destroy them.

**What Sarclisa 1400 mg solution for injection is and what it is used for**

Sarclisa is used to treat multiple myeloma, a cancer of the bone marrow.

Sarclisa is used with other medicines in adult patients.

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 a 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 1400 mg solution for injection**

**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.

**Systemic administration reactions (reactions to the active substance, isatuximab, that affects the whole body)**

The most common signs of systemic administration reactions to the injection include:

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

Severe symptoms of systemic administration reactions include:

- high blood pressure (hypertension)
- feeling extremely short of breath (dyspnoea)
- serious allergic reaction with breathing difficulty and swelling of the face, mouth, throat, lips or tongue.

Tell your doctor or nurse immediately if you have signs of systemic administration reactions during or after the injection of Sarclisa 1400 mg solution for injection.

- Before your first injection of Sarclisa 1400 mg solution for injection, you will receive other medicines to reduce the symptoms of the systemic administration reactions, at least for the first injections. It makes them less frequent and severe (see section 3 “How Sarclisa 1400 mg solution for injection is given”).
- Systemic administration reactions can happen during or after the injection of Sarclisa 1400 mg solution for injection, up to three days after administration. If you get a systemic administration 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.

**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 combination treatment with Sarclisa. Your doctor or nurse will monitor you for new cancers during treatment.

**Tumour lysis syndrome**

A fast breakdown of cancer cells (called tumour lysis syndrome) was reported with Sarclisa intravenous formulation. 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.

**Blood transfusion and Patient Card**
If you need a blood transfusion, you will have a blood test first to match your blood type. Tell the healthcare professional 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 last dose of this medicine.

This is also explained in the Patient Card that you have been given by your doctor.

Keep this Patient Card during treatment and for at least 6 months after the treatment has ended and share it with your healthcare team.

**Children and adolescents**

Sarclisa should not be used in children and adolescents under the age of 18. 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.

**Pregnancy, breastfeeding, and contraception**
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before being given Sarclisa.

**Pregnancy**

Use of Sarclisa is not recommended during pregnancy. If you are pregnant or planning to become pregnant, talk to your doctor about using Sarclisa.

**Breast-feeding**

Ask your doctor, pharmacist or nurse for advice before using Sarclisa.

- This is because Sarclisa may pass into the 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 should use an effective method of contraception during treatment and for 7 months after the last dose of Sarclisa. Talk to your doctor about the method of contraception that you should use during this time.

**Driving and using machines**

Sarclisa has mild to moderate influence on your ability to drive or use machines. However, if you feel tired or dizzy, do not drive or use machines until you feel better.

### 3. How Sarclisa 1400 mg solution for injection is given

**How much Sarclisa 1400 mg solution for injection is given**

The recommended dose of Sarclisa 1400 mg solution for injection is 1400 mg.

**How Sarclisa 1400 mg solution for injection is given**

Your doctor or nurse will prepare and inject your dose of Sarclisa 1400 mg solution for injection under your skin (subcutaneous injection). If you tolerate the treatment, your doctor may propose that you receive Sarclisa 1400 mg solution for injection at home.

- 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 injector) or a syringe to inject Sarclisa 1400 mg solution for injection. The injection will usually last less than 20 minutes with CirCLIQ on-body injector and 6 minutes with the syringe.
- Your doctor or nurse will make sure to rotate the injection site for each injection of Sarclisa 1400 mg solution for injection.
- Your doctor or nurse will use different places for injection for the other medicines that need to be injected.
- If you experience signs of systemic administration reactions, (see section 2 “What you need to know before you use Sarclisa 1400 mg solution for injection”) tell your doctor or nurse immediately.
- If you experience pain during the injection, the doctor or nurse may pause the injection and, if using a syringe, may give you the remaining injection in another area of your abdomen.

**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 who cannot receive their own stem cells (autologous bone marrow 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 who can receive their own stem cells (autologous bone marrow 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. Your doctor may increase the time between administrations based on how you tolerate your treatment.

You may start your treatment with Sarclisa given as an intravenous infusion (Sarclisa 20 mg/mL concentrate for solution for infusion) or as a subcutaneous injection (Sarclisa 1400 mg solution for injection). The doctor may decide to switch your treatment from intravenous infusions to subcutaneous injections, any time after the first cycle is completed.

**Medicines given before Sarclisa 1400 mg solution for injection**

You will be given the following medicines before administration of Sarclisa 1400 mg solution for injection. This is to help reduce the symptoms of the allergic reactions to Sarclisa injection:

- medicines to reduce allergic reactions (antihistamines and/or montelukast)
- medicines to reduce inflammation (corticosteroids)
- medicines to reduce pain and fever (such as paracetamol)

**If you miss a dose of Sarclisa**

It is very important that you meet 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 1400 mg solution for injection with you and will explain the possible risks and benefits of your treatment with Sarclisa 1400 mg solution for injection.

Tell your doctor or nurse immediately if you feel unwell during or after the injection of Sarclisa 1400 mg solution for injection (see section 2 “What you need to know before you use Sarclisa 1400 mg solution for injection”). Your doctor or nurse will monitor your condition closely during treatment.

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, lymphocytes) which help fight infection. This may lead to infections and fever.
  - infection of the upper airways (such as nose, sinuses or throat)
  - high blood pressure (hypertension)
  - diarrhoea
  - infections of lower airways, including pneumonia and bronchitis
  - tingling or numbness of the arms and legs (peripheral sensory neuropathy)
  - tiredness
  - feeling short of breath
  - constipation
  - difficulty sleeping
  - back pain
  - cough
  - joint pain
  - swelling of the ankles, feet or fingers (peripheral oedema)
  - nausea
  - clouding of your eye (cataract)
  - Covid-19
  - vomiting
  - lower number of blood cells called platelets which help to clot blood (thrombocytopenia) – tell your doctor or nurse if you have any unusual bruising or bleeding
  - fever
  - muscle spasm
  - arm and leg pain (pain in extremity)
  - rash
  - flu
  - 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
  - local skin reactions at or near the injection site including redness of the skin (erythema), itching, swelling, pain (injection site reactions)

- Common** (may affect up to 1 in 10 people):
  - dizziness
  - lower number of red blood cells (anaemia)
  - weight loss
  - new cancers, such as skin cancer
  - systemic administration reactions (reactions to the active substance (isatuximab) that affects the whole body) (see section 2 “What you need to know before you use Sarclisa 1400 mg solution for injection”)
  - decreased appetite
  - irregular heartbeat (atrial fibrillation)
  - herpes zoster (shingles)
  - heart problems, which may present as difficulty breathing, cough, or legs or feet swelling when Sarclisa is given with carfilzomib and dexamethasone

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](http://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 1400 mg solution for injection

Sarclisa 1400 mg solution for injection 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 the vials of Sarclisa 1400 mg solution for injection in a refrigerator (between 2°C and 8°C).

Unpunctured vials may be stored at room temperature (≤30°C) for a single period of up to 24 hours. Store in the original package in order to protect from light. Once the vial has been taken out of the refrigerator, it must not be returned to the refrigerator.

Do not freeze.

For storage conditions after insertion of the vial in CirCLIQ on-body injector or of the solution in the syringe for manual administration, see section below “Preparation and administration of Sarclisa 1400 mg solution for injection”.

For storage condition of CirCLIQ on-body injector, please refer to CirCLIQ on-body injector Instructions For Use.

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 1400 mg solution for injection contains**

- The active substance of Sarclisa 1400 mg solution for injection is isatuximab.
- One mL of solution contains 140 mg of isatuximab.
- Each vial of Sarclisa 1400 mg solution for injection contains 1400 mg of isatuximab in 10 mL of solution.
- The other ingredients (excipients) are arginine hydrochloride, sucrose, poloxamer 188, histidine, histidine hydrochloride monohydrate, and water for injections.

**What Sarclisa 1400 mg solution for injection looks like and contents of the pack**
Sarclisa 1400 mg solution for injection is a solution for injection. It is a colourless to slightly yellow liquid. The solution may contain a few translucent to white particles.

Pack size of one vial.

CirCLIQ on-body injector is packaged separately from Sarclisa 1400 mg solution for injection.

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**The following information is intended for healthcare professionals only:**

Sarclisa 1400 mg solution for injection vials are for single-use only. The injection solution must be prepared and administered by a healthcare professional. For the first dose only, immediate access to medical support should be available to manage systemic administration reactions (SARs) if they occur.

Once the cycle 1 is completed, subsequent subcutaneous injections may be administered at the patient’s home by a healthcare professional, as deemed appropriate, provided there were no SAR in the previous cycle.

In order to provide the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

**Preparation and administration of Sarclisa 1400 mg solution for injection**

**Preparation**

Sarclisa 1400 mg solution for injection should be administered by a healthcare professional.

- To prevent medication errors, check Sarclisa 1400 mg solution for injection vial label to ensure it is the correct medication for subcutaneous use (vial with green cap). **Do not administer Sarclisa 1400 mg solution for injection intravenously.**

Sarclisa 1400 mg solution for injection is ready to use.

Prepare and administer Sarclisa 1400 mg solution for injection subcutaneously using clean technique.

- Prior to use, allow Sarclisa 1400 mg solution for injection vial to reach room temperature for approximately 20 minutes to minimize pain during the injection. Keep the unpunctured vial in the original carton prior to use to protect from light. Do not heat. Do not shake.

Vials of Sarclisa 1400 mg solution for injection should be visually inspected before use. The solution may contain a few translucent to white particles. Sarclisa subcutaneous should not be used if the solution is cloudy or discoloured, or if particles other than those described above are present.

Sarclisa 1400 mg solution for injection is only for abdominal subcutaneous administration using:

- CirCLIQ On-Body Delivery System (OBDS) OR
- 20 mL syringe and infusion set for manual administration

**Preparation with CirCLIQ On-Body Delivery System**

- Refer to the Instructions for Use for CirCLIQ OBDS provided with the device for full preparation and administration information.
- Once the vial is punctured, the injection with the CirCLIQ On-Body Injector should be performed as soon as possible. CirCLIQ On-Body Injector should be used at temperature 18°C to 28°C and ambient light. If the injection is not completed within 4 hours, discard the vial and the On-Body Delivery System.

**Preparation with syringe and infusion set for manual administration**

- Before you begin, collect your supplies:
  - The syringe must be a 20 mL polypropylene syringe with Luer-fitting connector.
  - The transfer needle must be made of 18G stainless steel with 5-micron filter and Luer-fitting connector.
  - The subcutaneous infusion set must have 23G stainless steel needle and tubing up to 30 cm length made of polyethylene, or polyvinyl chloride, with a Luer-fitting connector.

Suitability of above materials for injection of Sarclisa subcutaneous was demonstrated in compatibility testing and clinical studies.

2. Check the expiration date.

- Remove green vial cap and wipe vial rubber stopper with an alcohol wipe and allow to air dry.

- Attach the transfer needle and fill the syringe.
  - Using the transfer needle, withdraw the full content of the Sarclisa 1400 mg solution for injection vial into a 20 mL compatible syringe.

Note: if the syringe containing Sarclisa 1400 mg solution for injection is not used immediately:

    - replace the transfer needle with a syringe closing cap. Label the syringe appropriately to include the drug name and route of administration per institutional standards.
    - store it for up to 4 hours at room temperature (15°C to 25°C) and ambient light, including the administration time.
  - Discard after 4 hours, if not used.

- Attach the subcutaneous infusion set to the syringe and set the dose.
  - Prime the syringe and subcutaneous infusion set and set the dose to 10 mL.

Note: To avoid needle clogging, attach the subcutaneous infusion set to the syringe immediately prior to injection.

**Administration**

- Sarclisa 1400 mg solution for injection is only for abdominal subcutaneous administration. Data are only available with an injection performed into the abdomen.
- Rotate the site of each subcutaneous administration.
- Do not inject other medications in the area where Sarclisa 1400 mg solution for injection is injected.
- Do not inject into areas where the skin is injured, tender, red, hot, has scars, or is excessively hairy.

**Administration with CirCLIQ On-Body Delivery System**

- Refer to the Instructions for Use for CirCLIQ OBDS provided with the device for full preparation and administration information.

**Administration with syringe and infusion set for manual administration**

- Prepare injection site and insert needle
  - Wipe injection site with an alcohol swab and allow it to dry
  - Avoid injecting within 5 cm around the belly button
  - Remove protective needle cover
  - Pinch skin at the injection site on the abdomen. It is important to pinch enough skin to inject under the skin and not into the muscle.
  - Insert needle at a 45-degree angle with a quick, dart-like motion.

Note: Try to limit needle and syringe movement during the injection. If needed, secure the subcutaneous infusion set in place with a bandage.

- Inject 10 mL of Sarclisa 1400 mg solution for injection into the abdomen, over approximately 6 minutes.

Pause or slow down delivery rate if the patient experiences pain. In the event pain is not alleviated by pausing or slowing down delivery rate, a second injection site may be chosen on the opposite side of the abdomen to deliver the remainder of the dose.

**Disposal**

Any unused medicinal product or waste material that have been utilised for the preparation and administration of isatuximab should be disposed of according to local standard requirements.