swissmedic

Summary report on authorisation dated 09 December 2025

Sarclisa® (active substance: isatuximab)

Indication extension in Switzerland: 19 May 2025

Concentrate for solution for infusion to treat adults with newly diagnosed multiple myeloma who are not eligible for an autologous stem cell transplant (ASCT), in combination with bortezomib, lenalidomide, and dexamethasone

About the medicinal product

The medicinal product Sarclisa, containing the active substance isatuximab, is a concentrate for solution for infusion and is used to treat adult patients with multiple myeloma. This is a form of blood cancer caused by malignant changes to the plasma cells in the bone marrow.

Sarclisa was first authorised on 18 March 2020 in combination with pomalidomide and dexamethasone for the treatment of recurrent, treatment-resistant multiple myeloma in adults who have already received at least 2 previous therapies, including lenalidomide and a proteasome inhibitor[1], and whose disease progressed during the last therapy.

On 22 December 2023, Sarclisa was also authorised in combination with carfilzomib and dexamethasone for the treatment of adults with multiple myeloma who have already received 1 or up to 3 previous treatments, and whose disease has nonetheless continued to progress.

This indication extension of 19 May 2025 means that Sarclisa can now also be used in combination with bortezomib, lenalidomide, and dexamethasone to treat adults with newly diagnosed multiple myeloma who are not eligible for an autologous stem cell transplant (ASCT)[2].

Since multiple myeloma is a rare, life-threatening disease, the medicinal product has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

This indication extension for Sarclisa was authorised as part of the joint initiative of the Access Consortium.

[1] Proteasome inhibitor: A medicinal product that blocks specific protein breakdown systems in cancer cells. This leads to harmful proteins accumulating in the cells, which stops the growth of the cancer cells and ultimately results in their death.

[2] Autologous stem cell transplant (ASCT): A treatment in which the patient's own stem cells are taken from their blood or bone marrow and reinfused after the patient has received intensive chemotherapy. This enables the haematopoietic ("blood-forming") system to recover and make new, healthy blood cells.

This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA), and Swissmedic. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least 2 of the 5 countries.
The authorisation application for this indication extension for Sarclisa was submitted to the drug regulatory authorities in Singapore and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the application independently.
Swissmedic considered the assessments by the foreign reference authority in its decision on the authorisation.

Further details of the Access joint initiative are published on the Swissmedic website: Access Consortium (swissmedic.ch).

Mode of action

Isatuximab, the active substance in Sarclisa, is a monoclonal antibody (an immunologically active protein) which binds in a targeted manner to a specific protein called CD38 that is found on the surface of cancer cells. By binding to CD38, isatuximab helps the immune system to destroy the cancer cells. It does so in a variety of ways: It activates the immune system to attack the cancer cells and can also directly stop the growth and division of the cancer cells. This varied action helps to slow down or stop the growth of the multiple myeloma.

Administration

Sarclisa is a prescription-only medicine and is administered intravenously (as an infusion into a vein) by a healthcare professional.
The recommended dose of Sarclisa is 10 mg per kg body weight. The infusion is administered in cycles. The treatment plan is based on the selected combination therapy and the patient's individual condition.

In order to reduce the risk or severity of infusion reactions, patients receive certain anti-allergy medicines 15 to 60 minutes before the infusion (premedication).
During the treatment there is a risk of neutropenia (very low number of a particular group of white blood cells). Severe neutropenia increases the risk of infection. The blood count therefore needs to be monitored regularly during the treatment.

Efficacy

The efficacy of Sarclisa was investigated in the IMROZ clinical trial. This trial assessed the combination of Sarclisa with bortezomib, lenalidomide, and dexamethasone (Isa-VRd) in patients with newly diagnosed multiple myeloma who are not eligible for an autologous stem cell transplant. The comparator treatment was the standard therapy comprising bortezomib, lenalidomide, and dexamethasone (VRd). A total of 446 patients were included in the trial, who were allocated 3:2 either to the Isa-VRd group or the VRd group, respectively.

After a median follow-up period[3] of 59.7 months, the trial showed longer progression-free survival (PFS)[4] in the Isa-VRd group compared to the VRd group: Median PFS could not yet be estimated in the Isa-VRd group and was 54.3 months in the VRd group. It is still too early to be able to conclusively assess overall survival (OS).

Precautions, undesirable effects, & risks

Sarclisa may not be used in those who are hypersensitive to the active substance or any of the excipients.

Infusion-related reactions (breathlessness, shortness of breath, high blood pressure, cough, chills, and nausea) occurred in the majority of the patients treated with Sarclisa.

Apart from the infusion-related reactions, the following frequent side effects (in more than 20% of all treated patients) may occur: upper respiratory tract infections, fatigue, and diarrhoea.

The most common serious side effect was pneumonia.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

There are currently only limited treatment options for patients with newly diagnosed multiple myeloma who are not eligible for an autologous stem cell transplant. Sarclisa, in combination with bortezomib, lenalidomide, and dexamethasone, covers this need. The clinical trial showed that this combination significantly improves progression-free survival (PFS) in the relevant patient group.

Taking all the risks and precautions into account, and based on the available data, the benefits outweigh the risks. Swissmedic has therefore approved this indication extension for Sarclisa, containing the active substance isatuximab, in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Sarclisa®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.

[3] Median follow-up period: The average length of time that patients in a trial are observed for, until half of the participants reach the end of the follow-up period or an event (e.g. disease progression or death) occurs.

[4] Progression-free survival (PFS): Period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.