swissmedic

Summary report on authorisation dated 20 December 2024

Sarclisa® (active substance: isatuximab)

Indication extension in Switzerland: 12 June 2023

Concentrate for solution for infusion for the treatment of multiple myeloma in adults in combination with carfilzomib and dexamethasone

About the medicinal product

Sarclisa contains the active substance isatuximab.

It is used to treat adults with multiple myeloma. This is a form of blood cancer caused by malignant changes to the plasma cells in the bone marrow.

Sarclisa is used in combination with other medicinal products (which contain the active substances carfilzomib and dexamethasone) in patients who have already received 1 or up to 3 previous treatments and whose disease has nonetheless continued to progress.

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

The medicinal product Sarclisa was authorised by Swissmedic on 18 March 2020 for the treatment of recurrent, treatment-resistant multiple myeloma in adults in combination with pomalidomide and dexamethasone. The indication extension means that Sarclisa can now also be used in combination with carfilzomib and dexamethasone to treat multiple myeloma in adults.

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.

Use

Sarclisa is a prescription-only medicine.

It 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 dose and treatment plan depend on the combination therapy and the patient's 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 IKEMA study in patients with relapsed (recurrent) and/or refractory multiple myeloma.

In this study, 179 patients received Sarclisa in combination with carfilzomib and dexamethasone (Isa-Kd) while 123 patients received carfilzomib and dexamethasone without Sarclisa (Kd). The primary objective of the study was an extension of progression-free survival (PFS[1]).

The results showed that patients in the Isa-Kd group had a significantly improved PFS versus the Kd group. Median[2] PFS in the Isa-K group was 35.65 months versus 19.15 months in the Kd group after a median follow-up period of 44 months.

Precautions, undesirable effects, & risks

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

Moderate to severe infusion-related reactions (breathlessness, shortness of breath, high blood pressure, cough, chills, and nausea) occurred in 44% 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 (14%).

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

[1] 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.

[2] The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always less than the median, the other half are always greater.

Why the medicinal product has been authorised

A significant extension of progression-free survival (PFS) and an improvement in response rates was achieved with the combination of Sarclisa with carfilzomib and dexamethasone.

Taking all the risks and precautions into account, and based on the available data, the benefits of the indication extension for Sarclisa outweigh the risks. Swissmedic has therefore authorised the indication extension of the medicinal product Sarclisa, containing the active substance isatuximab, for use 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.