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Sarclisa (*isatuximab*)

An overview of Sarclisa and why it is authorised in the EU

What is Sarclisa and what is it used for?

Sarclisa is a cancer medicine used together with the medicines pomalidomide and dexamethasone to treat multiple myeloma (a cancer of the bone marrow). It is given to adults who have received at least two previous treatments for their cancer, including lenalidomide and a proteasome inhibitor, and whose cancer has worsened since receiving the last treatment.

Multiple myeloma is rare, and Sarclisa was designated an 'orphan medicine' (a medicine used in rare diseases) on 29 April 2014. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/eu3141268.

Sarclisa contains the active substance isatuximab.

How is Sarclisa used?

Sarclisa can only be obtained with a prescription and should be given by a healthcare professional in a clinic or hospital where severe reactions can be quickly treated. It is given by infusion (drip) into a vein and the dose depends on body weight. Treatment starts with one dose of Sarclisa a week and, after a month, continues with one dose every two weeks. Before the infusion of Sarclisa, patients may be given medicines to reduce the risk of infusion-related reactions. The doctor may slow down the infusion or stop treatment in case of infusion-related reactions.

For more information about using Sarclisa, see the package leaflet or contact your doctor or pharmacist.

How does Sarclisa work?

The active substance in Sarclisa, isatuximab, is a monoclonal antibody (a type of protein) that has been designed to attach to the protein CD38, which is found in high amounts on multiple myeloma cells. By attaching to CD38 on the multiple myeloma cells, isatuximab activates the immune system (the body's natural defences) to kill the cancer cells.

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What benefits of Sarclisa have been shown in studies?

A main study in 307 patients with multiple myeloma that had not improved with previous treatments showed that adding Sarclisa to pomalidomide and dexamethasone can delay worsening of the disease. In this study, patients receiving Sarclisa and pomalidomide plus dexamethasone lived for 11.5 months without their disease getting worse compared with 6.5 months for patients receiving pomalidomide plus dexamethasone.

What are the risks associated with Sarclisa?

The most common side effects with Sarclisa (which may affect more than 1 in 5 people) are neutropenia (low levels of neutrophils, a type of white blood cell), infusion reactions, pneumonia (infection of the lungs), upper respiratory tract infection (such as nose and throat infections), diarrhoea and bronchitis (inflammation of the airways in the lungs).

The most common serious side effects are pneumonia and febrile neutropenia (low white blood cell counts with fever).

For the full list of side effects and restrictions with Sarclisa, see the package leaflet.

Why is Sarclisa authorised in the EU?

Sarclisa used together with pomalidomide plus dexamethasone extended the time patients with multiple myeloma lived without their disease getting worse. Sarclisa's side effects are as expected for this type of medicine given with pomalidomide and dexamethasone and are considered manageable. The European Medicines Agency therefore decided that Sarclisa's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Sarclisa?

The company that markets Sarclisa will provide educational material to all healthcare professionals expected to use the medicine to inform them that the medicine can affect the result of a blood test (indirect Coombs test) used to determine suitability for blood transfusions. Patients who are prescribed Sarclisa will be provided with a patient alert card with this information.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Sarclisa have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Sarclisa are continuously monitored. Side effects reported with Sarclisa are carefully evaluated and any necessary action taken to protect patients.

Other information about Sarclisa

Sarclisa received a marketing authorisation valid throughout the EU on 30 May 2020.

Further information on Sarclisa can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/sarclisa.

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