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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 to treat multiple myeloma (a cancer of the bone marrow). It is given:

- together with the medicines pomalidomide and dexamethasone to treat adults who have received at least two previous treatments, including lenalidomide and a proteasome inhibitor, and whose cancer has worsened since receiving the last treatment;
- together with the medicines carfilzomib and dexamethasone to treat adults who have received at least one previous treatment;
- together with the medicines bortezomib, lenalidomide and dexamethasone to treat adults who have not received previous treatment and who cannot receive an autologous stem cell transplant (a transplant of the patient's own blood-producing cells).

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. How often Sarclisa is given depends on whether patients have received previous treatments for their disease. Treatment is continued until the disease gets worse or the side effects become unacceptable. 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

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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.

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.

A second main study in 302 adults with multiple myeloma who had received one to three previous treatments showed that adding Sarclisa to carfilzomib and dexamethasone can delay worsening of the disease. In this study, over an average of 21 months, about 27% of patients (48 out of 179) receiving Sarclisa with carfilzomib plus dexamethasone experienced worsening of their disease, compared with about 45% (55 out of 123) of those receiving carfilzomib plus dexamethasone.

A third main study in 446 adults with newly diagnosed multiple myeloma who had not received previous treatments and who could not be treated with an autologous stem cell transplant, showed that adding Sarclisa to bortezomib, lenalidomide and dexamethasone can delay worsening of the disease. In this study, over an average of 60 months, the disease had worsened in 32% (84 out of 265) of patients given Sarclisa together with bortezomib, lenalidomide and dexamethasone, compared with 43% (78 out of 181) of those only treated with bortezomib, lenalidomide and dexamethasone.

What are the risks associated with Sarclisa?

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

The most common side effects with Sarclisa used with pomalidomide and dexamethasone (which may affect more than 1 in 5 people) include 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 with Sarclisa when used with pomalidomide and dexamethasone include pneumonia and febrile neutropenia (low white blood cell counts with fever).

The most common side effects with Sarclisa used with carfilzomib and dexamethasone (which may affect more than 1 in 5 people) include infusion reactions, hypertension (high blood pressure), diarrhoea, upper respiratory tract infection, pneumonia, tiredness, dyspnoea (difficulty breathing), insomnia (difficulty sleeping), bronchitis and back pain. The most common serious side effect with Sarclisa used with carfilzomib and dexamethasone is pneumonia.

The most common side effects with Sarclisa used with bortezomib, lenalidomide and dexamethasone (which may affect more than 1 in 5 people) include diarrhoea, peripheral sensory neuropathy (nerve damage that affects the sensation of pain, temperature and touch), pneumonia, cataract (clouding of the eye lens), constipation, tiredness, upper respiratory tract infections, peripheral oedema (swelling, especially of the ankles and feet), neutropenia, infusion reactions, insomnia, COVID-19 infection, back pain, bronchitis and weakness. The most common serious side effects with Sarclisa used with bortezomib, lenalidomide and dexamethasone is pneumonia.

Why is Sarclisa authorised in the EU?

Sarclisa, used together with other medicines to treat multiple myeloma, extended the time patients lived without their disease getting worse. Sarclisa's side effects are as expected for this type of

medicine 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 blood banks as well as healthcare professionals expected to prescribe 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.

This overview was last updated in 12-2024.