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Sarclisa® (active substance: isatuximab)

First authorisation in Switzerland: 18.03.2020

Concentrate for solution for infusion for the treatment of adult patients with relapsed and refractory multiple myeloma, together with other medicines containing the active substances pomalidomide and dexamethasone

About the medicine

The medicinal product Sarclisa, containing the active substance isatuximab, is a concentrate for solution for infusion (medicine administered as a fluid through the veins) and was authorised in Switzerland on 18 March 2020. Sarclisa is used together with other medicines containing the active substances pomalidomide and dexamethasone. It has been authorised for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies (including with the active substance lenalidomide or with a proteasome inhibitor) and have demonstrated disease progression on the last therapy.

Multiple myeloma is a rare form of bone marrow cancer in which malignant plasma cells (specific white blood cells) reproduce and proliferate at several (multiple) sites in the bone marrow and destroy bone.

Mode of action

The active substance in Sarclisa, isatuximab, is a specialised protein that binds to the protein named CD 38 and located on the diseased cells. This process triggers various mechanisms that kill the cancer cells, thereby lowering the risk of disease progression.

Use

Sarclisa is administered into the vein by a healthcare professional and may only be used in an environment (hospital, clinic, medical practice) where the necessary resuscitation facilities are available.
The recommended dose of Sarclisa is 10 mg per kg body weight. Sarclisa is administered in combination with other medicines containing pomalidomide and dexamethasone according to a specific treatment schedule that must be strictly observed. This treatment schedule is described in the Information for healthcare professionals.

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). Since severe neutropenia increases the risk of infection, the blood count must be monitored regularly during treatment.

Efficacy

The efficacy of Sarclisa, with the active substance isatuximab, was investigated in a study with 301 patients. All study participants had received at least two prior therapies which had either proved ineffective or lost their efficacy.

One group of study participants received the standard treatment with the active substances pomalidomide and low-dose dexamethasone. The other group received Sarclisa in combination with the standard treatment pomalidomide and low-dose dexamethasone.

The study showed that patients who received the Sarclisa in combination with the standard treatment survived for longer without disease progression compared to those patients who only received the standard treatment (active substances pomalidomide and dexamethasone without Sarclisa).

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 (dyspnoea (shortness of breath), high blood pressure, cough, chills and nausea) occurred in 37% of the patients treated with Sarclisa, but these usually subsided during the course of the day. Apart from the infusion-related reactions, the following frequent side effects (in more than 20% of all treated patients) may occur:
Neutropenia (very low number of a particular group of white blood cells), upper respiratory tract infections, fatigue, pneumonia, diarrhoea, constipation. 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.

Why the medicine has been authorised

Although much progress has been made in recent years in the treatment of multiple myeloma, the disease remains incurable.

The study showed that patients who received the Sarclisa in combination with the medicines containing the active substances pomalidomide and dexamethasone survived for longer without worsening of the disease than patients who received the standard treatment (only pomalidomide and low-dose dexamethasone).

It was also noticed that almost twice as many patients who received the Sarclisa in combination with the standard treatment were still in treatment after the end of the study. More patients who only received the standard treatment stopped taking the treatment due to a worsening of the disease, but also due to adverse events.

Taking all the precautions into account, and based on the available data, the benefits of Sarclisa outweigh the risks. Swissmedic has therefore authorised the medicine Sarclisa with 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 (doctors, pharmacists and others) can answer any further questions.

This information is correct as at the date above. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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