Myeloma Patients Europe

FACTSHEET

MYELOMA PATIENTS EUROPE

ISATUXIMAB (SARCLISA®)

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Edition: Myeloma Patients Europe (MPE)
Updated: February 2022

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FACTSHEET

MYELOMA PATIENTS EUROPE

Myeloma Patients Europe (MPE) has developed a series of factsheets for patients and patient advocates, providing an overview of available treatment options for myeloma and covering some topics related to the disease.

The factsheets cover important issues around the treatment, so that patients can feel safe and ask their doctor specific questions.

For each of the available therapies, the following topics will be addressed:

- What is myeloma?
- What is the particular treatment?
- How does the treatment work?
- What are the benefits?
- What are the side-effects?
- How and when is the treatment given?

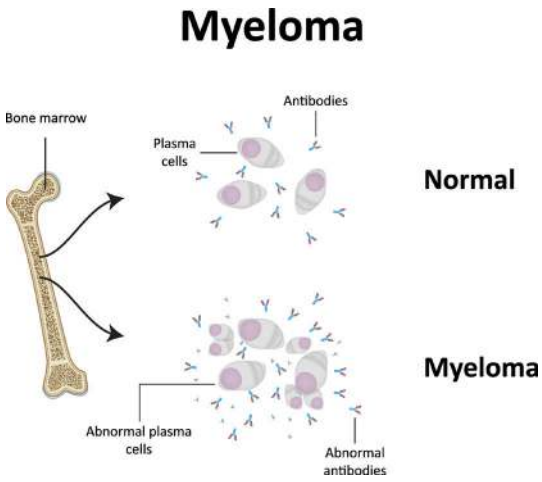
Myeloma treatment is constantly evolving and the factsheets will be updated regularly to reflect the latest developments.

What is myeloma?

Myeloma is a rare cancer of the bone marrow. It causes the formation of abnormal plasma cells, also called myeloma cells, which divide uncontrollably. Usually, plasma cells help the body to fight infections by making antibodies that recognise and attack viruses, bacteria, and other cancer cells. Myeloma affects multiple places in the body (this is why it is sometimes referred to as 'multiple myeloma') where bone marrow is normally active, such as the bones of the spine, pelvis, rib cage and the areas around the shoulders and hips.

Myeloma causes pain, anaemia (low red blood cells), fatigue, fractures, recurring infection, bruising and high blood calcium (hypercalcaemia). These symptoms usually require treatment, which could be followed by a period of remission where symptoms subside and may not require any treatment. This cycle of remission and recurrence (relapse) often occurs several times. Many patients, particularly in relapse setting, will be on treatment for a long period of time to ensure that their myeloma is kept at bay.

Treatment may involve taking a combination of drugs that have been found to be more effective than single drugs. Myeloma generally cannot be cured, but survival rates are increasing, due to the availability of new treatments and many patients are able to enjoy a good quality of life. A number of other new treatments have recently been approved or are under consideration for use following relapse, or for refractory myeloma.



What is isatuximab (Sarclisa®)?

Isatuximab is a monoclonal antibody (mAb, a laboratory manufactured antibody) drug indicated together with pomalidomide and dexamethasone for the treatment of multiple myeloma. It is administered to adults who have received at least two previous lines of therapy, including lenalidomide and a proteasome inhibitor, and whose myeloma has progressed since receiving the last treatment [3,1]. Isatuximab is also recommended in combination with carfilzomib and dexamethasone for the treatment of adult multiple myeloma patients who have received at least one prior line of therapy[2,4].

As multiple myeloma is considered a 'rare disease' because it affects such a small number of people, isatuximab was granted 'orphan drug designation' by the European Commission in 2014. An orphan drug designation is a status assigned to medicines developed for rare disease conditions that affect fewer than 5 patients per 10,000 inhabitants in the EU[1]. It received a marketing authorisation valid throughout the EU on 30 May 2020.[3]

How does isatuximab work?

Isatuximab binds to the CD38 protein present on the surface of myeloma cells. By binding to this protein, isatuximab induces the death of myeloma cancer cells (also called apoptosis). Also, by binding to the CD38 protein on the surface of the myeloma cell, isatuximab activates the immune system by marking the myeloma cells for destruction.[2]

What are the benefits of isatuximab?

The safety and efficacy of isatuximab has been evaluated in several studies. In the ICARIA-MM study[1] that included 307 participants, isatuximab was administered in combination with pomalidomide and dexamethasone. Patients who received isatuximab lived about 12 months without worsening of their myeloma, while for patients who did not receive isatuximab this period lasted about 6 months.

What are the side-effects of isatuximab?

The most common side effects of isatuximab are[1,2,3,4]:

- Neutropenia (low levels of neutrophils, a type of white blood cell also known as an immune cell)
- Infusion reactions which occur during or shortly after infusion
- Pneumonia (infection of the lungs)
- Upper respiratory tract infection (such as nose and throat infections)
- Diarrhoea
- Bronchitis (inflammation of the airways in the lungs)

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

How and when is isatuximab given?

Isatuximab is given by infusion (drip) at a dose of 10 mg/kg of body weight once per week for the first cycle of treatment. Cycles are defined as periods of treatment (usually 28 days). After the initial cycle, one dose of isatuximab is given every two weeks. Before infusion, 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[2].

References

1. Attal, M. et al. Isatuximab plus pomalidomide and low-dose dexamethasone versus pomalidomide and low-dose dexamethasone in patients with relapsed and refractory multiple myeloma (ICARIA-MM): a randomised, multicentre, open-label, phase 3 study. The Lancet 394, 2096–2107 (2019)

2. "Dailymed - SARCLISA- Isatuximab Injection, Solution, Concentrate". Dailymed.Nlm.Nih.Gov, 2022: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a0473462-6f9d-4eca-a5bf-8620aea68e8a.

3. "Sarclisa - European Medicines Agency". European Medicines Agency, 2022: https://www.ema.europa.eu/en/medicines/human/EPAR/sarclisa.

4. Moreau P, et al. "Isatuximab, carfilzomib, and dexamethasone in relapsed multiple myeloma (IKEMA): a multicentre, open-label, randomised phase 3 trial." Lancet. 2021;397(10292):2361-2371.

MPE is a network of European myeloma patient organisations. It supports national patient organisations to improve treatment and access for patients in their countries and helps inform and raise awareness on a European level through its educational programmes. Please note, this information does not replace the information provided by your doctor. If there is anything that is not clear to you, please always ask your clinical team.

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