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Elrexfio (*elranatamab*)

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

What is Elrexfio and what is it used for?

Elrexfio is a cancer medicine used to treat adults with multiple myeloma (a cancer of the bone marrow) when the cancer has come back (relapsed) and has not responded to treatment (refractory). It can be used in adults who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody, and whose cancer has worsened since the last treatment.

Elrexfio contains the active substance elranatamab.

How is Elrexfio used?

Elrexfio can only be obtained with a prescription and treatment must be started and monitored by a doctor experienced in the management of multiple myeloma.

The medicine must be given by adequately trained medical personnel in a location with appropriate medical support to manage possible severe side effects such as cytokine release syndrome (CRS, a potentially life-threatening overactivation of the immune system with fever, shortness of breath, low blood pressure and headache) and immune effector cell-associated neurotoxicity syndrome (ICANS, a neurological disorder with symptoms including problems with speech and writing, confusion and reduced level of consciousness).

Elrexfio is given as an injection under the skin. In the first week of treatment, injections are given on days 1 and 4 at increasing doses and then weekly up to week 24. Patients who respond to treatment can then continue with one injection every two weeks.

To reduce the risk of developing CRS, patients are given medicines one hour before receiving the first three doses of Elrexfio. Patients should be monitored for symptoms of CRS or ICANS for 48 hours after the first two doses of Elrexfio.

Treatment should continue for as long as the patient benefits from it or until side effects become unmanageable. The doctor may delay doses if certain side effects occur or stop treatment altogether for certain severe side effects. For more information about using Elrexfio, see the package leaflet or contact your doctor or pharmacist.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How does Elrexfio work?

The active substance in Elrexfio, elranatamab, is a bispecific antibody (a type of protein). It is designed to recognise and attach to two targets simultaneously: the B cell maturation antigen (BCMA) on the surface of cancer cells and CD3 on the surface of T cells (cells in the immune system). By attaching to these targets, this medicine brings the cancer cells and T cells together. This activates the T cells, which then kill myeloma cells.

What benefits of Elrexfio have been shown in studies?

Elrexfio was shown to be effective at clearing the cancer in an ongoing study. This study involved 123 patients with multiple myeloma whose disease had stopped responding to and had come back after three previous therapies (including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody). Patients had not received prior treatment targeting BCMA on myeloma cells. In this study, 61% (75 of 123) of patients responded to treatment with Elrexfio, including 36% (44 out of 123) who had a complete response (no signs of cancer). The study did not compare Elrexfio with other medicines or placebo (a dummy treatment).

What are the risks associated with Elrexfio?

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

The most common side effects with Elrexfio (which may affect more than 1 in 5 people) include CRS, anaemia (low levels of red blood cells), neutropenia (low levels of neutrophils, a type of white blood cell), fatigue (tiredness), infection of the upper respiratory tract (nose and throat), injection site reactions, diarrhoea, pneumonia (infection of the lungs), thrombocytopenia (low levels of blood platelets, components that help the blood to clot), lymphopenia (low levels of lymphocytes, a type of white blood cell), decreased appetite, fever, rash, arthralgia (joint pain), hypokalaemia (low blood potassium levels), nausea (feeling sick) and dry skin.

Serious side effects include pneumonia, sepsis (blood poisoning), CRS, anaemia, upper respiratory tract infection, infection of the urinary tract (parts of the body that collect and pass out urine), febrile neutropenia (low levels of white blood cells with fever), dyspnoea (difficulty breathing) and fever.

Why is Elrexfio authorised in the EU?

At the time of approval, the European Medicines Agency considered that there was an unmet medical need for patients with multiple myeloma whose condition no longer improves with available therapies. These patients, who have limited treatment options, had a clinically meaningful response to treatment with Elrexfio, as shown by the proportion of patients who had either a complete or partial response within the main study. Overall, the safety profile was considered acceptable; the Agency considered that important safety concerns, such as CRS and ICANS, are reversible and manageable with standard treatment. Due to the lack of a comparator and the short duration of follow-up of patients in the main study, a number of uncertainties remain regarding the safety and effectiveness of Elrexfio; it is expected that these will be addressed by further data that will be submitted by the company.

Elrexfio has been given 'conditional authorisation'. This means that that the Agency decided that the benefits of Elrexfio are greater than its risks, but the company will have to provide additional evidence after authorisation.

Conditional authorisation is granted on the basis of less comprehensive data than are normally required. It is granted for medicines that fulfil an unmet medical need to treat serious diseases and when the benefits of having them available earlier outweigh any risks associated with using the

medicines while waiting for further evidence. Every year, the European Medicines Agency will review any new information that becomes available until comprehensive data are available and this overview will be updated as necessary.

Since Elrexfio was given conditional authorisation, at the time of approval the company marketing Elrexfio was required to submit the final results of the ongoing study in patients with multiple myeloma who were treated with Elrexfio. In addition, they have to provide data from a study that compares the effectiveness of both Elrexfio given on its own and in combination with daratumumab (another cancer medicine) with that of other treatments currently authorised for the same use.

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

The company that markets Elrexfio will provide patients with an alert card that contains information about the risk of CRS and side effects affecting the nervous system, including ICANS. The alert card also notifies healthcare professionals that the patient is receiving treatment with Elrexfio.

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

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

Other information about Elrexfio

Elrexfio received a conditional marketing authorisation valid throughout the EU on 07 December 2023.

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

This overview was last updated in 12-2023.