EMA/236687/2022
EMEA/H/C/005680

Lunsumio (*mosunetuzumab*)

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

What is Lunsumio and what is it used for?

Lunsumio is a cancer medicine used to treat adults with follicular lymphoma that does not respond to (refractory), or has come back (relapsed) after, at least two previous treatments.

Follicular lymphoma is a cancer that affects a type of white blood cell called B lymphocytes.

Follicular lymphoma is rare, and Lunsumio was designated an 'orphan medicine' (a medicine used in rare diseases) on 16 November 2021. Further information on the orphan designation can be found on the EMA website.

Lunsumio contains the active substance mosunetuzumab.

How is Lunsumio used?

Lunsumio can only be obtained with a prescription and must be given under the supervision of a doctor who is qualified in the use of cancer medicines.

Lunsumio should be given in a facility with appropriate medical support to manage severe side effects such as cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). For more information about these possible side effects, see the section on risks below.

Lunsumio is given as an infusion (drip) into a vein or as an injection under the skin of the thigh or abdomen, in treatment cycles of 3 weeks. During the first cycle, the patient receives one infusion or injection a week, and each infusion lasts a few hours. In later cycles, one infusion or injection is given every 3 weeks, and the infusion may be given quicker if previous infusions were well tolerated.

Treatment with Lunsumio usually lasts 8 cycles, but up to 17 cycles may be given depending on how well the disease responds to treatment. However, the doctor may interrupt or stop treatment if the patient develops severe side effects.

To reduce the risk of CRS and infusion-related reactions, patients are given medicines before their first two doses of Lunsumio. If these reactions occur, patients will continue to receive these medicines before later doses.

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

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How does Lunsumio work?

The active substance in Lunsumio, mosunetuzumab, is a monoclonal antibody (a type of protein) designed to attach to CD20, found on B lymphocytes, including the follicular lymphoma cells.

It also attaches to CD3, a protein found on T cells, another type of white blood cell. T cells are part of the immune system (the body's natural defences). They help protect the body from infection and can also destroy cancer cells.

By attaching to both CD20 and CD3, Lunsumio brings the cancer cells and T cells together. This encourages T cells to destroy the follicular lymphoma cells.

What benefits of Lunsumio have been shown in studies?

The benefits of Lunsumio were evaluated in a study in adults with relapsed or refractory follicular lymphoma who had received at least two previous treatments. In this study, Lunsumio was not compared with any other medicines. In response to treatment, 80% (72 out of 90) of participants had their cancer shrink or disappear, with 54 out of 90 patients (60%) achieving a complete response (no detectable signs of cancer). On average, responses lasted for at least 12 months in 62% of patients.

What are the risks associated with Lunsumio?

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

The most common side effects with Lunsumio (which may affect more than 2 in 10 people) include cytokine release syndrome (a potentially life-threatening condition causing fever, vomiting, shortness of breath, headache and low blood pressure), neutropenia (low levels of neutrophils, a type of white blood cell), rash and upper respiratory tract infection (nose and throat infection).

Some side effects can be serious. The most frequent (which may affect more than 2 in 100 people) include cytokine release syndrome, fever, sepsis (when bacteria and their toxins circulate in the blood, leading to organ damage), upper respiratory tract infection and pneumonia (infection of the lungs).

Why is Lunsumio authorised in the EU?

Patients with relapsed or refractory follicular lymphoma have limited treatment options. Treatment with Lunsumio resulted in a complete response (no detectable signs of cancer) in more than half of the patients. Regarding safety, side effects were considered generally manageable and acceptable for the disease it is used for.

Lunsumio has been given 'conditional authorisation'. This means that is has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need. The Agency considers that the benefits of having the medicine available earlier outweigh any risks associated with using it while waiting for further evidence.

The company must provide further data on Lunsumio. It must submit results from an ongoing study comparing Lunsumio with rituximab, both given with lenalidomide, in patients with follicular lymphoma who had received at least one previous treatment. Every year, the Agency will review any new information that becomes available.

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

The company that markets Lunsumio must provide a patient card to all patients receiving the medicine. The card explains key signs and symptoms of CRS and ICANS, and advises on when to seek urgent medical help.

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

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

Other information about Lunsumio

Lunsumio received a conditional marketing authorisation valid throughout the EU on 3 June 2022.

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

This overview was last updated in 10-2025.