



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 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 here: ema.europa.eu/medicines/human/orphan-designations/EU3212517.

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, in a location with appropriate medical support to manage severe side effects such as cytokine release syndrome (see risks section below).

Lunsumio is given as an infusion (drip) into a vein. Infusions with Lunsumio should be given once a week in the first cycle, then once every three weeks for subsequent cycles (each cycle takes three weeks), for a total of 8 treatment cycles. However, depending on side effects and how the disease responds to treatment, up to 17 cycles may be given. For the first cycle, infusions should last four hours, but subsequent infusions may be given more quickly if treatment is tolerated well. The doctor may interrupt or stop treatment if the patient develops certain serious side effects.

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

How does Lunsumio work?

Follicular lymphoma is a cancer that affects a type of white blood cell called B lymphocyte. The active substance in Lunsumio, mosunetuzumab, is a monoclonal antibody (a type of protein) that has been designed to attach to CD20, a protein found on B lymphocytes, including the cancer cells, and to CD3, a protein on T cells (a different type of white blood cell). T cells are a part of the body's defences and help protect the body from infection. They can also destroy cancer cells.

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By binding to the CD20 and CD3 proteins, the medicine acts like a bridge to bring together the cancer cells and T cells. This encourages the T cells to destroy the cancer cells and helps control the disease.

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 therapies. In this study, Lunsumio was not compared with other medicines. In response to treatment, the cancer shrank or disappeared in 80% (72 out of 90) of patients, while 60% (54 out of 90) of patients achieved a complete response (no sign of cancer). On average, responses lasted for at least 12 months in 62% of patients.

What are the risks associated with Lunsumio?

The most common side effects with Lunsumio (which may affect more than 2 in 10 people) are 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), fever, low levels of phosphate in the blood and headache. The most common serious side effects included cytokine release syndrome, fever and pneumonia (infection of the lungs).

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

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 in a high proportion of these patients, and side effects were considered generally manageable and acceptable. The European Medicines Agency therefore decided that Lunsumio's benefits are greater than its risks and that it can be authorised for use in the EU.

Lunsumio has been given 'conditional authorisation'. This means that there is more evidence to come about the medicine, which the company is required to provide. Every year, the Agency will review any new information that becomes available. This medicine overview will be updated as necessary.

What information is still awaited for Lunsumio?

Since Lunsumio has been given conditional authorisation, the company that markets Lunsumio will provide results from an ongoing study comparing Lunsumio with rituximab, both given with lenalidomide, in patients with follicular lymphoma who had at least one previous treatment for their disease.

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

The company that markets Lunsumio must provide patient cards with information about key signs and symptoms of cytokine release syndrome, and when and where to seek help if such signs occur. This card will also inform healthcare professionals that the patient is receiving Lunsumio.

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 06-2022.