

Package leaflet: Information for the patient

Lunsumio 1 mg concentrate for solution for infusion Lunsumio 30 mg concentrate for solution for infusion mosunetuzumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lunsumio is and what it is used for
2. What you need to know before you use Lunsumio
3. How to take Lunsumio
4. Possible side effects
5. How to store Lunsumio
6. Contents of the pack and other information

1. What Lunsumio is and what it is used for

Lunsumio contains the active substance mosunetuzumab, which is a type of antibody. This is a cancer medicine. It is used to treat adults who have a blood cancer called follicular lymphoma (FL).

In FL, a type of white blood cells called ‘B cells’ become cancerous. The abnormal B cells do not work properly and grow too quickly, crowding out the normal B cells in the bone marrow and lymph nodes that help protect you from infection.

Lunsumio is given to patients who have tried at least two previous treatments for FL, when either the cancer has not responded to them, or it has come back again.

How Lunsumio works

The active substance in Lunsumio, mosunetuzumab, is a monoclonal antibody, a type of protein that attaches to specific targets in the body. In this case, mosunetuzumab attaches to a target substance found on B cells, including the cancerous B cells, and another target found on ‘T cells’, a different type of white blood cell. T cells are another part of the body’s defences that can destroy invading cells. By attaching the two cells together like a bridge, Lunsumio encourages the T cells to destroy the cancerous B cells. This helps control the FL and prevent its spread.

2. What you need to know before you use Lunsumio

You must not be given Lunsumio

- if you are allergic to mosunetuzumab or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor or nurse before you are given Lunsumio.

Warnings and precautions

Talk to your doctor or nurse before you are given Lunsumio if any of the following apply to you (or you are not sure):

- you have ever had heart, lung or kidney problems
- you have an infection, or have had an infection in the past which lasted a long time or keeps coming back
- you are due to have a vaccine or you know you may need to have one in the near future.

If any of the above apply to you (or you are not sure), talk to your doctor or nurse before having this medicine.

Tell your doctor straight away if you get symptoms of any of the side effects listed below during or after treatment with Lunsumio. You may need additional medical treatment. The symptoms of each side effect are listed in section 4.

- **Cytokine release syndrome (CRS)** – a condition associated with medicines that stimulate T cells.
 - Before each infusion, you may be given medicines, which help reduce possible side effects of cytokine release syndrome.
 - Haemophagocytic lymphohistiocytosis is a condition where the immune system makes too many infection-fighting cells called histiocytes and lymphocytes. Signs and symptoms may overlap with CRS, your doctor will check for this condition if your CRS does not respond to treatment or lasts longer than expected.
- **Immune effector cell-associated neurotoxicity syndrome (ICANS)** – a condition associated with effects on the nervous system. Symptoms include feeling confused, problems with memory, language or judgement, disorientation and confusion often accompanied by hallucination (seeing, hearing or feeling things that are not there), and not being able to concentrate.
- **Tumour lysis syndrome** – some people may get unusual levels of some salts in the blood – caused by the fast breakdown of cancer cells during treatment.
 - Your doctor or nurse will do blood tests to check for this condition. Before each infusion, you should be well-hydrated and may be given medicines that can help reduce high levels of uric acid. These may help reduce possible side effects of tumour lysis syndrome.
- **Tumour flare** – as your cancer is destroyed, it may react and appear to get worse – this is called ‘tumour flare reaction’.
- **Infections** – you may get signs of infection, which can vary depending on where in the body the infection is.

Children and adolescents

This medicine should not be used in children or adolescents under the age of 18. This is because there is no information about use in this age group.

Other medicines and Lunsumio

Tell your doctor if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines.

Pregnancy and breast-feeding

It is important to tell your doctor before and during treatment if you are pregnant, think you may be pregnant, or are planning to get pregnant. This is because Lunsumio may affect your unborn baby.

- Do not use Lunsumio during pregnancy, unless after discussion with your doctor, it is agreed that the benefits of treatment outweigh any risk to the unborn baby.

Contraception

Women who could become pregnant must use effective contraception during treatment – and for 3 months after the last dose of Lunsumio.

- Talk to your doctor or nurse about suitable methods of contraception.

Breast-feeding

You must not breast-feed during and for at least 3 months after your last treatment. This is because it is not known whether any Lunsumio passes into breast milk and could therefore affect the baby.

Driving and using machines

Lunsumio has major influence on your ability to drive, cycle or use any tools or machines. Due to the possible symptoms of ICANS, you should be careful while driving, cycling or using heavy or potentially dangerous machines. If you currently have such symptoms, avoid these activities and contact your doctor, nurse, or pharmacist. See section 4 for more information about side effects.

3. How Lunsumio is given

Lunsumio is given under the supervision of a doctor experienced in giving such treatments. Follow the treatment schedule explained to you by your doctor. Check with your doctor if you are not sure.

How Lunsumio is given

It is given into a vein, as a drip (infusion).

- It is given over 4 hours during the first cycle. Each cycle is 21 days and in the first cycle, you will be given the 4 hour infusion on day 1, day 8 and day 15.
- If side effects are not too severe, the dose may be given over 2 hours during the following cycles.

Medicines given before Lunsumio treatment

You may be given other medicines 30 to 60 minutes before you are given Lunsumio. This is to help prevent infusion reactions and fever. These other medicines may include:

- Corticosteroids – such as dexamethasone or methylprednisolone
- Paracetamol
- An antihistamine - such as diphenhydramine

How much Lunsumio is given

Lunsumio is normally given in cycles of 21 days. The recommended treatment duration is at least 8 treatment cycles. However, depending on side effects and how the disease responds to treatment, you may be given up to 17 cycles.

In cycle 1, you will be given 3 doses of Lunsumio in the 21 days:

- Day 1: 1 mg
- Day 8: 2 mg
- Day 15: 60 mg

In cycle 2, you will be given just one dose:

- Day 1: 60 mg

In cycles 3 to 17, you will be given just one dose:

- Day 1: 30 mg

If you miss a dose of Lunsumio

If you miss an appointment, make another one straight away. For the treatment to be fully effective, it is very important not to miss a dose.

If you stop receiving Lunsumio

Do not stop treatment with Lunsumio unless you have discussed this with your doctor. This is because stopping treatment may make your condition worse.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Tell your doctor straight away if you notice any of the symptoms of the following serious side effects. You may only get one or some of these symptoms.

Cytokine release syndrome

Symptoms can include:

- fever (38°C or higher)
- chills or shaking chills
- cold or pale clammy skin
- difficulty breathing
- feeling dizzy or lightheaded
- fast or uneven heartbeat
- confusion
- feeling very tired or weak
- fainting
- blurred vision
- headache.

Haemophagocytic lymphohistiocytosis

Symptoms can include:

- fever
- enlarged liver and/or spleen
- skin rash
- lymph node enlargement
- easy bruising
- kidney abnormalities
- breathing problems
- heart problems

Tumour lysis syndrome

Symptoms can include:

- fever

- chills
- feeling or being sick (nausea and vomiting)
- confusion
- being short of breath
- fits (seizures)
- uneven heartbeat
- dark or cloudy urine
- unusual tiredness
- muscle or joint pain.

Shown in blood tests

- increase in potassium, phosphate or uric acid – which can cause kidney problems (part of tumour lysis syndrome)

Tumour flare

Symptoms can include:

- tender swollen lymph nodes
- chest pain
- cough or difficulty breathing easily
- pain at the site of the tumour.

Infections

Symptoms can include:

- fever
- cough
- chest pain
- tiredness
- shortness of breath
- painful rash
- sore throat
- burning pain when passing urine
- feeling weak or generally unwell.

Immune effector cell-associated neurotoxicity syndrome (ICANS)

The symptoms can occur days or weeks after you receive the injection and may initially be subtle.

Symptoms can include:

- confusion/disorientation
- tiredness
- altered mental state
- lowered mental state
- impaired memory

If you have any of these symptoms after treatment with Lunsumio, tell your doctor straight away. You may need medical treatment.

Other side effects

Very common: may affect more than 1 in 10 people

- Rash
- Itchy skin
- Dry skin
- Diarrhoea
- Headache
- Fever

- Chills
- Cytokine release syndrome

Shown in blood tests

- Low levels of some white blood cells (neutropenia)
- Low number of red blood cells, which can cause tiredness and shortness of breath
- Low platelet count, which may make you more likely to bruise or bleed (thrombocytopenia)
- Low level of phosphate, potassium or magnesium
- High level of alanine aminotransferase in the blood

Common: may affect up to 1 in 10 people

- Lung infection
- Infection of upper airways (infection of nose, throat, sinuses)
- Urinary tract infection
- Fever due to low levels of neutrophils (a type of white blood cell)
- Tumour flare
- A serious immune reaction affecting the nervous system (immune effector cell-associated neurotoxicity syndrome)

Shown in blood tests

- Increased levels of liver enzymes, which may be a sign of liver problems

Uncommon: may affect up to 1 in 100 people

- A rapid breakdown of tumour cells resulting in chemical changes in the blood and damage to organs, including the kidneys, heart, and liver (tumour lysis syndrome)
- A condition where the immune system makes too many infection-fighting cells called histiocytes and lymphocytes (haemophagocytic lymphohistiocytosis).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: <http://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lunsumio

Lunsumio will be stored by the healthcare professionals at the hospital or clinic. The storage details that they must take account of are as follows

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and the vial after EXP. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C – 8°C).
- Do not freeze.
- The diluted solution should not be kept more than 24 hours at 2°C – 8°C and 24 hours at ambient temperature (9°C – 30°C).
- Keep the container in the outer carton in order to protect from light.

Your healthcare professional will dispose of any unneeded medicine appropriately. These measures will help protect the environment.

6. Contents of the pack and other information

What Lunsumio contains

- The active substance is mosunetuzumab.

- Lunsumio 1 mg: Each vial contains 1 milligram (mg) mosunetuzumab in 1 mL at a concentration of 1 mg/mL.
- Lunsumio 30 mg: Each vial contains 30 milligrams (mg) mosunetuzumab in 30 mL at a concentration of 1 mg/mL.
- The other ingredients are: L-histidine, L-methionine, acetic acid, sucrose, polysorbate 20 (E432), water for injections.

What Lunsumio looks like and contents of the pack

Lunsumio is a concentrate for solution for infusion (sterile concentrate). It is a clear, colourless liquid provided in a glass vial.

Each pack of Lunsumio contains one vial.

Marketing Authorisation Holder and Manufacturer

Roche Products Limited
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Welwyn Garden City
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United Kingdom

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This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine.

The following information is intended for healthcare professionals only:

Procedures for proper handling and disposal of anticancer medicinal products should be considered.

Instructions for dilution

1. Withdraw and discard a volume of sodium chloride 9 mg/mL (0.9%) solution for injection or sodium chloride 4.5 mg/mL (0.45%) solution for injection equal to the volume of the Lunsumio required for the patient’s dose from the infusion bag according to the Table 6 below.
2. Withdraw the required volume of Lunsumio from the vial using a sterile syringe and dilute into the infusion bag. Discard any unused portion left in the vial.

Table 6: Dilution of Lunsumio

Day of treatment		Dose of Lunsumio	Volume of Lunsumio in sodium chloride 9 mg/mL (0.9%) or 4.5 mg/mL (0.45%) solution for injection	Size of infusion bag
Cycle 1	Day 1	1 mg	1 mL	50 mL or 100 mL
	Day 8	2 mg	2 mL	50 mL or 100 mL
Cycle 2	Day 1	60 mg	60 mL	100 mL or 250 mL
	Day 5	60 mg	60 mL	100 mL or 250 mL
Cycle 3	Day 1	30 mg	30 mL	100 mL or 250 mL

and beyond				
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3. Gently mix the infusion bag by slowly inverting the bag. Do not shake.
4. Inspect the infusion bag for particulates and discard if present.
5. Apply the peel-off label from the leaflet to the infusion bag.

Diluted solution

The product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2 °C to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

Peel-off label



Peel and apply this label to the infusion bag