



SCHEDULING STATUS

S4

LUNSUMIO 1 mg/1 mL; Concentrate for solution for infusion

LUNSUMIO 30 mg/30 mL; Concentrate for solution for infusion

The active substance is mosunetuzumab

Contains sugar (sucrose) 82,1 mg for 1 mg/1 mL vial,
and 2462,4 mg for 30 mg/30 mL vial

Read all of this leaflet carefully before you start taking Lunsumio

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed on this leaflet.

What is in this leaflet

1. What Lunsumio is and what it is used for
2. What you need to know before you take Lunsumio
3. How Lunsumio is given to you
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

What Lunsumio is

Lunsumio is a cancer medicine that contains the active substance mosunetuzumab

What Lunsumio is used for

Lunsumio is used to treat follicular lymphoma (FL). It is used when:

- the cancer did not respond to two or more previous treatments for FL or
- the cancer has come back after two or more previous treatments

'B cells' are a type of white blood cell that help your body fight infection. In FL, some B cells become cancerous and they multiply quickly. This means that they replace normal cells in the lymph nodes and bone marrow (where blood cells are made).

How Lunsumio works

'T cells' are another type of white blood cell - Lunsumio attaches to the B cells, including cancerous B cells, and T cells.

- This means it acts as a bridge between the two cells.
- This allows the T cells to kill the B cells.

2. What you need to know before you are given Lunsumio

You must not be given Lunsumio

- if you are allergic to mosunetuzumab or any of the other ingredients of Lunsumio (see Section 6 What Lunsumio Contains and What Lunsumio Looks Like for a complete list of ingredients in Lunsumio).

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



Warnings and precautions

Talk to your doctor before you are given Lunsumio if:

- you have ever had heart, lung or kidneys 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.

Look out for serious side effects

Lunsumio can cause some serious side effects. These include:

- **Cytokine release syndrome** – collection of symptoms that can develop as a side effect of certain types of therapy, especially those which involve T-cells. Signs and symptoms vary in different people
- Tell your doctor or nurse straight away if you get any symptoms of this syndrome – these are listed in section 4.

Before each infusion, you may be given medicines which help reduce possible side effects of cytokine release syndrome.

- **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.
- Tell your doctor or nurse straight away if you get any symptoms of this syndrome – these are listed in section 4.



- Your doctor, pharmacist or nurse will do blood tests to check for this condition. Before each infusion, you may be given medicines which help reduce possible side effects of tumour lysis syndrome.
- **Tumour flare** – your cancer may appear to get worse – this is called ‘tumour flare reaction’.
- Tell your doctor or nurse straight away if you get any symptoms of tumour flare – these are listed in section 4.
- **Infections** – signs and symptoms of infections vary in different people
- Tell your doctor or nurse straight away if you get any symptoms of an infection – these are listed in section 4.

If you had any of these symptoms after treatment with [Tradename], tell your doctor straight away if you notice any changes in them. You may need medical treatment.

If you have any of the above symptoms tell your doctor straight away.

Your doctor may:

- give you other medicines to reduce symptoms and prevent complications
- stop your treatment for a short time, or
- stop your treatment completely

Pregnancy and contraception

- Tell your doctor if you are pregnant, think you might be pregnant, or are planning to become pregnant. This is because Lunsumio may affect your unborn baby.
- You should not be given Lunsumio if you are pregnant, unless your doctor thinks that it is the best medicine for you.
- If you could become pregnant, you must use effective contraception while you are being treated with Lunsumio and for 3 months after the last dose.
- If you become pregnant while you are being treated with Lunsumio tell your doctor immediately.



Breast-feeding

Do not breast-feed while receiving Lunsumio and for at least 3 months after the last dose. This is because it is not known if this medicine can pass into breast milk and harm your baby.

Children and adolescents (< 18 years)

Lunsumio should not be used in children or adolescents under 18 years of age. This is because Lunsumio has not been studied in this age group.

Taking other medicines and Lunsumio

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

Ability to drive and use machines

Lunsumio is likely to affect your ability to drive, cycle, or use any tools or machines.

If you feel any symptoms that may affect your ability to drive, do not drive, cycle, or use any tools or machines until you feel better. See section 4 for more information about side effects

Important information about some of the ingredients of Lunsumio

Xofluza contains sucrose. Patients with the rare hereditary conditions of sucrose intolerance should not take Lunsumio.

Lunsumio contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How Lunsumio is given to you

You will be given Lunsumio under the supervision of a doctor experienced in cancer treatment, in a hospital or clinic.



It is given into a vein, as a drip.

- It is given over 4 hours during the first cycle
- If well tolerated, it is given over 2 hours during the following cycles.

Medicines given before Lunsumio treatment

- During the 30 to 60 minutes before you are given Lunsumio, you may be given other medicines (pre-medication) to help reduce reactions and fever. These medicines may include:
 - Corticosteroid such as dexamethasone or methylprednisolone
 - Paracetamol
 - An antihistamine such as diphenhydramine

How much and how often you will receive Lunsumio

You will be given 8 treatment cycles and possibly more – up to a maximum of 17 cycles

Each cycle lasts 21 days- this is a typical schedule:

Cycle 1 – this will include 3 doses of [Tradename] in the 21 days:

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

Cycle 2 – just one dose:

- Day 1 – 60 mg

Cycles 3 to 17 – 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.

Before stopping Lunsumio treatment

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

Ask your doctor if you have any further questions on the use of this medicine.

4. Possible side effects

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

Serious side effects

Tell your doctor immediately if you get any of the serious side effects listed below – you may need urgent medical treatment.

Cytokine release syndrome

- 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 or blurred vision
- headache.
- fits (seizures)
- uneven heartbeat



- dark or cloudy urine
- unusual tiredness
- muscle or joint pain

Shown in tests

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

Tumour flare

- tender swollen lymph nodes
- chest pain
- cough or unable to breathe easily
- pain at the site of the tumour.

Infections

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

If you have any of these symptoms after treatment with [Tradename], tell your doctor straight away.

You may need medical treatment.



Other side effects

Tell your doctor or nurse if you notice any of the following side effects or if they get worse:

Very common (may affect more than 1 in 10 people)

- Rash or itchy skin or dry skin
- Diarrhoea
- Headache
- Fever

Shown in 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

Common: may affect up to 1 in 10 people

- Lung infection
- Infection of upper airways (infection of nose, pharynx, larynx, sinuses)
- Urinary tract infection
- Fever due to low levels of neutrophils (a type of white blood cell) Shown in tests
- Increased levels of liver enzymes

Reporting of side effects

If you get side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form",

found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of LUNSUMIO.

5. How to store Lunsumio

Lunsumio will be stored by your doctor at the hospital or clinic. The storage details 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 at 2°C – 8°C.
- Do not freeze.
- Do not shake.
- 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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

Lunsumio is for single use only. Any unused product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What Lunsumio contains

- The active substance is mosunetuzumab.
- Lunsumio 1 mg/2 mL: Each vial contains 1 milligrams of mosunetuzumab (in 2 mL).
- Lunsumio 30 mg/50 mL: Each vial contains 30 milligrams of mosunetuzumab (in 50 mL).

The other ingredients are: as registered locally.

- L-Histidine,
- L-Methionine,
- Acetic acid,



- Sucrose,
- Polysorbate 20,
- Water for Injection
-

What Lunsumio looks like

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

Each pack of Lunsumio contains one vial.

Holder of Certificate of Registration

Roche Products (Pty) Ltd

90 Bekker Road

Hertford Office Park

Building E, Vorna Valley

Midrand, 1685

South Africa

Roche Ethical Assistance Line toll-free: 0800 21 21 25

This leaflet was last revised in

Registration date: 18 March 2025

Registration number

57/30.1/0372-3