

MEDICATION GUIDE
LUNSUMIO™ (lun-SUM-mee-oh)
(mosunetuzumab-axgb)
injection, for intravenous infusion

What is the most important information I should know about LUNSUMIO?

LUNSUMIO may cause Cytokine Release Syndrome (CRS), a serious side effect that is common during treatment with LUNSUMIO, and can also be severe or life-threatening.

Get medical help right away if you develop any signs or symptoms of CRS at any time, including:

- fever of 100.4°F (38°C) or higher
- chills
- low blood pressure
- fast or irregular heartbeat
- tiredness or weakness
- difficulty breathing
- headache
- confusion
- feeling anxious
- dizziness or light-headedness
- nausea
- vomiting

Due to the risk of CRS, you will receive LUNSUMIO on a “step-up dosing schedule”.

- The step-up dosing schedule is when you receive smaller “step-up” doses of LUNSUMIO on Day 1 and Day 8 of your first cycle of treatment.
- You will receive a higher dose of LUNSUMIO on Day 15 of your first cycle of treatment.
- If your dose of LUNSUMIO is delayed for any reason, you may need to repeat the “step-up dosing schedule.”
- Before each dose in Cycle 1 and Cycle 2, you will receive medicines to help reduce your risk of CRS.
- See **“How will I receive LUNSUMIO?”** for more information about how you will receive LUNSUMIO.

Your healthcare provider will check you for CRS during treatment with LUNSUMIO and may treat you in a hospital if you develop signs and symptoms of CRS. Your healthcare provider may temporarily stop or completely stop your treatment with LUNSUMIO if you have severe side effects.

See **“What are the possible side effects of LUNSUMIO?”** for more information about side effects.

What is LUNSUMIO?

LUNSUMIO is a prescription medicine used to treat adults with follicular lymphoma whose cancer has come back or did not respond to previous treatment, and who have already received two or more treatments for their cancer.

It is not known if LUNSUMIO is safe and effective in children.

Before receiving LUNSUMIO, tell your healthcare provider about all of your medical conditions, including if you:

- have ever had an infusion reaction after receiving LUNSUMIO.
- have an infection or have had an infection in the past which lasted a long time or keeps coming back.
- have or had Epstein-Barr Virus.
- are pregnant or plan to become pregnant. LUNSUMIO may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with LUNSUMIO.

Females who are able to become pregnant:

- your healthcare provider should do a pregnancy test before you start treatment with LUNSUMIO.
- you should use an effective method of birth control (contraception) during your treatment and for 3 months after the last dose of LUNSUMIO.
- are breastfeeding or plan to breastfeed. It is not known if LUNSUMIO passes into your breast milk. Do not breastfeed during treatment and for 3 months after the last dose of LUNSUMIO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive LUNSUMIO?

- LUNSUMIO will be given to you by your healthcare provider by infusion through a needle placed in a vein (intravenous infusion).
- After you complete the weekly “step-up dosing schedule” in Cycle 1, LUNSUMIO is given every 21 days.
- After Cycle 1 and Cycle 2, your healthcare provider will decide if you need to continue to take other medicines to help reduce side effects from LUNSUMIO during future cycles.
- Your healthcare provider will decide how many treatment cycles you will receive of LUNSUMIO.

See “**What is the most important information I should know about LUNSUMIO?**” for more information about how you will receive LUNSUMIO.

What should I avoid while receiving LUNSUMIO?

Do not drive, operate heavy machinery, or do other dangerous activities if you develop dizziness, confusion, tremors, sleepiness, or any other symptoms that impair consciousness until your signs and symptoms go away. These may be signs and symptoms of CRS or neurologic problems.

See “**What is the most important information I should know about LUNSUMIO?**” and “**What are the possible side effects of LUNSUMIO?**” for more information about signs and symptoms of CRS and neurologic problems.

What are the possible side effects of LUNSUMIO?

LUNSUMIO may cause serious side effects, including:

See “**What is the most important information I should know about LUNSUMIO?**”

- **neurologic problems.** LUNSUMIO can cause serious and life-threatening neurologic problems. Your healthcare provider will check you for neurologic problems during treatment with LUNSUMIO. Your healthcare provider may also refer you to a healthcare provider who specializes in neurologic problems. Tell your healthcare provider right away if you develop any signs or symptoms of neurologic problems during or after treatment with LUNSUMIO, including:
 - headache
 - numbness and tingling of the arms, legs, hands, or feet
 - dizziness
 - confusion and disorientation
 - difficulty paying attention or understanding things
 - forgetting things or forgetting who or where you are
 - trouble speaking, reading, or writing
 - sleepiness or trouble sleeping
 - tremors
 - loss of consciousness
 - seizures
 - muscle problems or muscle weakness
 - loss of balance or trouble walking
 - tiredness
- **serious infections.** LUNSUMIO can cause serious infections that may lead to death. Your healthcare provider will check you for signs and symptoms of infection before and during treatment. Tell your healthcare provider right away if you develop any signs or symptoms of infection during treatment with LUNSUMIO, including:
 - fever of 100.4°F (38°C) or higher
 - cough
 - chest pain
 - tiredness
 - shortness of breath
 - painful rash
 - sore throat
 - pain during urination
 - feeling weak or generally unwell
- **hemophagocytic lymphohistiocytosis (HLH).** LUNSUMIO can cause overactivity of the immune system, a condition called hemophagocytic lymphohistiocytosis (HLH). HLH can be life-threatening and has led to death in people treated with LUNSUMIO. Your healthcare provider will check you for HLH especially if your CRS lasts longer than expected. Signs and symptoms of HLH include:
 - fever
 - enlarged spleen
 - easy bruising
 - low blood cell counts
 - liver problems
- **low blood cell counts.** Low blood cell counts are common during treatment with LUNSUMIO and can also be serious or severe.

Your healthcare provider will check your blood cell counts during treatment with LUNSUMIO. LUNSUMIO can cause the following low blood cell counts:

 - **low white blood cell counts (neutropenia).** Low white blood cells can increase your risk for infection.
 - **low red blood cell counts (anemia).** Low red blood cells can cause tiredness and shortness of breath.
 - **low platelet counts (thrombocytopenia).** Low platelet counts can cause bruising or bleeding problems.

- **growth in your tumor or worsening of tumor related problems (tumor flare).** LUNSUMIO can cause serious or severe worsening of your tumor.

Tell your healthcare provider if you develop any of these signs or symptoms of tumor flare during your treatment with LUNSUMIO:

- chest pain
- cough
- trouble breathing
- tender or swollen lymph nodes
- pain or swelling at the site of the tumor

Your healthcare provider may temporarily stop or permanently stop treatment with LUNSUMIO if you develop severe side effects.

The most common side effects of LUNSUMIO include: tiredness, rash, fever, and headache.

The most common severe abnormal blood test results with LUNSUMIO include: decreased phosphate, increased glucose, and increased uric acid levels.

These are not all the possible side effects of LUNSUMIO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of LUNSUMIO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about LUNSUMIO that is written for health professionals.

What are the ingredients in LUNSUMIO?

Active ingredient: mosunetuzumab-axgb

Inactive ingredients: acetic acid, histidine, methionine, polysorbate 20, sucrose, and Water for Injection

Manufactured by: **Genentech, Inc.**, A Member of the Roche Group, 1 DNA Way, South San Francisco, CA 94080-4990

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For more information, call 1-844-832-3687 or go to www.LUNSUMIO.com.