

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **ELREXFIO™**

(elranatamab injection)

Read this carefully before you start receiving **Elrexio** and each time you get an injection. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Elrexio**.

Serious Warnings and Precautions

- A serious side effect called cytokine release syndrome (CRS), which can be severe or fatal, may occur. Symptoms usually include fever (38°C or higher) and chills. Other symptoms of CRS may include difficulty in breathing, dizziness or feeling light-headed, feeling the need to throw up, headache, fast heartbeat, low blood pressure, feeling tired, vomiting, muscle pain and joint pain.
- Serious or life-threatening neurologic problems may occur after taking Elrexio. Symptoms may include headache, confusion, difficulty with memory, difficulty speaking or slow speech, difficulty understanding speech, difficulty in writing, being confused about time or surroundings, being less alert, or excessive sleepiness, and seizures (fits). Some of these may be signs of a serious immune reaction called ‘immune effector cell associated neurotoxicity syndrome’ (ICANS). These effects can occur days or weeks after you receive the injection, and may be subtle at first.
- Your healthcare provider will monitor for signs and symptoms of CRS and neurological problems during treatment with Elrexio. You should call your healthcare provider right away if you develop any of the signs and symptoms of CRS or neurologic problems at any time during your treatment with Elrexio.

What is Elrexio used for?

- Elrexio is a cancer medicine that contains the active substance “elranatamab” and is used to treat adults with a type of cancer of the bone marrow called multiple myeloma.
- It is used for patients who have had at least three different treatments that have not worked or have stopped working.

“For the following indication(s) Elrexio has been approved with conditions (NOC/c). This means it has passed Health Canada’s review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.”

- the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 3 prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

How does Elrexio work?

Elrexio is an antibody, a type of protein which has been designed to recognize and attach to specific targets in your body. Elrexio targets B cell maturation antigen (BCMA), which is found on multiple myeloma cancer cells, and cluster of differentiation 3 (CD3), which is found on T cells of your immune system. This medicine works by attaching to these cells and bringing them together, so that your immune system can kill the multiple myeloma cancer cells.

What are the ingredients in Elrexio?

Medicinal ingredients: elranatamab

Non-medicinal ingredients: edetate disodium dihydrate, L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose, water for injection.

Elrexio comes in the following dosage forms:

- Solution for injection, 44 mg/1.1 mL (40 mg/mL)
- Solution for injection, 76 mg/1.9 mL (40 mg/mL)

Do not use Elrexio if:

- you are allergic to elranatamab or any of the other ingredients of this medicine. If you are not sure if you are allergic, talk to your doctor or nurse before you are given Elrexio.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Elrexio. Talk about any health conditions or problems you may have, including if you:

- had any infection within the last 4 weeks. Before you are given Elrexio, your doctor will check your blood counts for signs of infection. If you have any infection, it will be treated before you start Elrexio.
- are pregnant or plan to become pregnant. Elrexio may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Elrexio passes into your breast milk. You must not breastfeed during treatment and for 5 months after stopping treatment with Elrexio.
- could become pregnant. You must use effective contraception during treatment and for 5 months after stopping treatment with Elrexio.
- had a recent vaccination or are going to have a vaccination. You should not receive live vaccines from four weeks before until four weeks after you are treated with Elrexio.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Other warnings you should know about:

- Do not drive, use tools, operate heavy or potential dangerous machinery, or do things that could pose a danger to yourself until at least 48 hours after each of your 2 step-up doses, or as instructed by your healthcare provider. Some people may feel tired, dizzy, or confused while receiving Elrexio.

How you will receive Elrexio:

- Your healthcare provider will give you Elrexio through an injection under your skin (“subcutaneous” injection). It is given in the stomach area (abdomen) or thigh.

Usual dose:

- The dose of Elrexio solution for subcutaneous injection is 76 mg, but the first two doses will be lower. Elrexio is given as follows:
 - You will receive a “Step-up dose 1” of 12 mg on Week 1: Day 1
 - You will then receive a “Step-up dose 2” of 32 mg on Week 1: Day 4
 - You will then receive a “Treatment dose” of 76 mg on Week 2: Day 1
 - You will then continue receiving a “Treatment dose” once a week from Week 3 to Week 24, as long as you are getting benefit from Elrexio.
 - You will then continue receiving a “Treatment dose” once every other week from Week 25 onwards, as long as you are getting benefit from Elrexio.
- You will be given other medicines 1 hour before each of your first three doses of Elrexio, which help lower the chance of side effects, such as cytokine release syndrome. These may include:
 - Medicine to reduce the risk of fever (such as acetaminophen)
 - Medicine to reduce the risk of inflammation (corticosteroids)
 - Medicine to reduce the risk of an allergic reaction (antihistamines such as diphenhydramine)
- You may also be given these medicines for later doses of Elrexio based on any symptoms you have.
- You may also be given additional medicines based on any symptoms you experience or your medical history.
- Your doctor will monitor you for side effects for 48 hours after each of your first two doses (step-up doses). You should stay close to a healthcare facility for 48 hours after the first two doses in case you have side effects. Your doctor may recommend that you stay in the hospital after the first two doses.
- Your doctor will regularly check your blood counts, as the number of blood cells and other blood components may decrease.

Overdose:

This medicine will be given by your doctor or nurse. In the unlikely event that you are given too much, your doctor will monitor you for side effects.

If you think you, or a person you are caring for, have taken too much Elrexfio, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

It is very important to go to all your appointments to make sure your treatment works.

If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment. It is important for you to be monitored closely for side effects during treatment with Elrexfio.

What are possible side effects from using Elrexfio?

These are not all the possible side effects you may have when taking Elrexfio. If you experience any side effects not listed here, tell your healthcare professional.

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

- Low levels of red blood cells (anemia)
- Feeling tired or weak
- Edema (excess fluid in body tissue, causing swelling of the hands and feet)
- Diarrhea, feeling sick (nausea), constipation, vomiting
- Low levels of blood platelets (cells that help blood to clot, thrombocytopenia)
- Nose and throat infection (upper respiratory tract infection)
- Lung infection (pneumonia)
- Low levels of types of white blood cells (lymphopenia, leucopenia)
- Decreased appetite
- Pain in your joints
- Fever
- Skin reactions at or near the injection site, including redness of the skin, itching, swelling, pain, bruising, rash, or bleeding
- Low level of “potassium” in the blood (hypokalemia)
- Dry skin
- Skin rash
- Increased level of liver enzymes “transaminases” in the blood
- Cough
- Being short of breath (dyspnea)
- Bladder infection (urinary tract infection)

Common (may affect up to 1 in 10 people):

- Low level of “phosphate” in the blood (hypophosphatemia)
- Low number of a type of white blood cell with a fever (febrile neutropenia)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Cytokine Release Syndrome (CRS) (serious immune reaction): fever (38°C or higher), chills, nausea, headache, fast heartbeat, feeling dizzy or lightheadedness, confusion or restlessness, and difficulty breathing		√	√
Hypogammaglobulinemia: low levels of antibodies called “immunoglobulins” in the blood which may make infections more likely		√	
Neutropenia: low levels of a type of white blood cells, fever, general weakness, tendency to develop infections		√	
Infection: fever, chills, shivering, cough, shortness of breath, rapid breathing, and rapid pulse		√	√
COMMON			
Neurologic problems, including Immune effector cell associated neurotoxicity syndrome (ICANS) (effects on the nervous system): headache, agitation, trouble staying awake, feeling confused, feeling less alert, having difficulty writing, having trouble speaking, tremors, problems walking, muscle weakness, numbness and tingling		√	√
UNCOMMON			
Liver problems (increased liver enzymes in your blood): tiredness, loss of appetite, pain in your right upper stomach-area (abdomen), dark urine, yellowing of your skin or the white part of your eyes		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Elrexio will be stored at the hospital or clinic by your doctor.

Keep out of reach and sight of children.

Store in a refrigerator (2°C to 8°C). Do not freeze. Do not shake.

Store in the original carton in order to protect from light.

If you want more information about Elrexio:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <https://www.pfizer.ca>, or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC

Last Revised: DEC 06, 2023