ELREXFIO®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using ELREXFIO?

ELREXFIO is a cancer medicine that contains the active ingredient elranatamab. ELREXFIO is used to treat adults with cancer of the bone marrow called multiple myeloma. It is used for patients who have had at least three other kinds of treatment which have not worked or have stopped working. For more information, see Section 1. Why am I using ELREXFIO? in the full CMI.

2. What should I know before I use ELREXFIO?

Do not use ELREXFIO if you have ever had an allergic reaction to elranatamab or any of the ingredients listed at the end of the CMI.

ELREXFIO may cause side effects that are serious, life-threatening or lead to death, including allergic reactions, cytokine release syndrome (CRS), infections, neurological problems including a serious immune reaction called immune effector cell-associated neurotoxicity syndrome (ICANS) and blood abnormalities.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I use ELREXFIO? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ELREXFIO and affect how it works. For more information see Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use ELREXFIO?

ELREXFIO is a ready-to-use solution given to you under the supervision of an experienced healthcare professional as an injection under your skin (subcutaneous injection), usually in your stomach area or thigh.

More information can be found in Section 4. How do I use ELREXFIO? in the full CMI.

5. What should I know while using ELREXFIO?

Things you should do	• Carry the ELREXFIO Patient Card with you at all times. • Remind any doctor, dentist or pharmacist you visit that you are using ELREXFIO. • Tell your doctor if you have had an infection, had a recent vaccination or are scheduled to receive a vaccination, are pregnant or planning to become pregnant or breastfeeding or plan to breastfeed.
Things you should not do	• Do not stop using ELREXFIO suddenly. • Do not receive live vaccines within 4 weeks before, during treatment, and at least 4 weeks after treatment with ELREXFIO.
Driving or using machines	• Do not drive, use tools, operate heavy or dangerous machinery during treatment with ELREXFIO and for at least 48 hours after each of your 2 step-up doses. ELREXFIO may cause neurological problems that make you feel tired, less alert, dizzy or confused.
Looking after your medicine	• ELREXFIO will be stored refrigerated at the hospital or clinic.

For more information, see Section 5. What should I know while using ELREXFIO? in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see Section 6. Are there any side effects? of the full CMI for more details). ELREXFIO may cause serious side effects including allergic reactions, CRS, neurological problems such as ICANS, infections and blood abnormalities. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WARNING: ELREXFIO may cause side effects that are serious, life-threatening or lead to death including cytokine release syndrome (CRS) and neurological toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS). Call your health professional right away if you develop any of the signs or symptoms of CRS or ICANS listed below:

CRS - Fever, chills, nausea, headache, fast heartbeat, feeling dizzy, difficulty breathing.

ICANS - Numbness and tingling (feeling like pins and needles), confusion, trouble speaking, muscle spasms, tremor, changes in your handwriting, problems walking, muscle weakness, burning, throbbing or stabbing pain

ELREXFIO® (el-'reks-fē-ō)

Active ingredient: elranatamab

This medicine has **provisional approval** in Australia for relapsed or refractory multiple myeloma in adults who have received at least 3 prior therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody and have demonstrated disease progression on the last therapy. The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

Consumer Medicine Information (CMI)

This leaflet provides important information about using ELREXFIO.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ELREXFIO.

Where to find information in this leaflet:

1. Why am I using ELREXFIO?
2. What should I know before I use ELREXFIO?
3. What if I am taking other medicines?
4. How do I use ELREXFIO?
5. What should I know while using ELREXFIO?
6. Are there any side effects?
7. Product details

1. Why am I using ELREXFIO?

ELREXFIO is a cancer medicine that contains the active ingredient elranatamab.

ELREXFIO is used to treat adults with cancer of the bone marrow called multiple myeloma. It is used for patients who have had at least three other kinds of treatment that have not worked or have stopped working.

ELREXFIO is an antibody, a type of protein which has been designed to recognise and attach to specific targets in your body.

ELREXFIO targets proteins found on cells in the blood:

- B-cell maturation antigen (BCMA), found on multiple myeloma cancer cells
- Cluster of differentiation 3 (CD3), found on T cells of your immune system.

This medicine works by attaching to the proteins on these cells, so that your immune system can destroy the multiple myeloma cancer cells.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

2. What should I know before I use ELREXFIO?

Warnings

ELREXFIO may cause side effects that are serious, life-threatening or lead to death, including allergic reactions, cytokine release syndrome (CRS), infections, neurological problems including a serious immune reaction called immune effector cell-associated neurotoxicity syndrome (ICANS) and blood abnormalities. Due to the risk of severe reactions, hospitalisation is recommended for step-up dosing and when therapy is re-started.

See additional information under Section 6. Are there any side effects?

You will receive an ELREXFIO Patient Card from your doctor or pharmacist.

Always carry the ELREXFIO Patient Card with you and show it to healthcare professionals involved in your care and if you go to the Emergency Department.

The ELREXFIO Patient Card lists symptoms of CRS and neurological problems, including ICANS.

Get medical help right away if you develop any of the symptoms listed on the ELREXFIO Patient Card.

You may need to be treated in a hospital.

Do not use ELREXFIO if:

- you are allergic to elranatamab, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

- Always check the ingredients to make sure you can use this medicine.

If you are not sure whether you should start using this medicine, talk to your doctor.

Check with your doctor if you:

- Have had fever, chills or any other signs or symptoms of infection.

  Low numbers of white blood cells can increase your risk of infection.

- Have had abnormal blood test results.

  Decreased numbers of white blood cells, red blood cells and platelets are very common while you are using ELREXFIO. Low numbers of red blood cells can increase tiredness and shortness of breath and make your skin paler than normal. Low numbers of platelets can increase your risk of bleeding. Your doctor will monitor you with regular blood tests to check for changes in the levels of your blood cells.

- Have or have had kidney problems.
- Have or have had liver problems.
- Take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Vaccinations

Tell your doctor if you had a recent vaccination or are scheduled to receive a vaccine.

You should not receive a live vaccine within 4 weeks before you start treatment with ELREXFIO, during treatment, and at least 4 weeks after treatment with ELREXFIO. If you are not sure about the type of vaccine, ask your healthcare provider.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

ELREXFIO may harm your unborn baby. Your healthcare provider should do a pregnancy test before you start treatment with ELREXFIO if you are of childbearing age.

If you are of childbearing age, you should use effective contraception during treatment and for 4 months after your last dose of ELREXFIO.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if ELREXFIO passes into your breast milk. Do not breastfeed during treatment and for 4 months after your last dose of ELREXFIO.

Children and Adolescents

Do not give ELREXFIO to children or young people below 18 years of age. This is because it is not known how ELREXFIO will affect them.

ELREXFIO is not addictive.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ELREXFIO and affect how it works.

When you start ELREXFIO treatment your body releases proteins called cytokines which are made by certain immune and non-immune cells and have an effect on the immune system. The release of cytokines may affect how other medicines work.

The highest risk for an interaction between the release of cytokines and other medicines you are taking is:

- during the step-up dosing schedule. See Section 4. How do I use ELREXFIO?

- after a side effect called CRS. Your doctor will monitor and adjust other medicines you take during this period.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ELREXFIO.

4. How do I use ELREXFIO?

How ELREXFIO is given

- You will receive ELREXFIO under the supervision of an experienced healthcare professional.
- ELREXFIO will always be given to you as an injection under the skin (subcutaneous injection).
- ELREXFIO is given in the stomach area or thigh.

How much to use

- The dose of ELREXFIO is 76 mg, but the first two doses you receive will be lower.

When to use ELREXFIO

- 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 'full treatment dose' of 76 mg on Week 2: Day 1.
- You will then continue receiving a 'full treatment dose' once a week from Week 3 to Week 24, as long as you are getting benefit from ELREXFIO.
- You will then continue receiving a 'full treatment dose' once every other week from Week 25 to Week 48, as long as you are getting benefit from ELREXFIO.
- You will then continue receiving a 'full treatment dose' once every 4 weeks from Week 49 onwards, as long as you are getting benefit from ELREXFIO.

Other medicines given during treatment with ELREXFIO

You will be given medicines 1 hour before each of your first three doses of ELREXFIO, which help to lower the chance of side effects such as CRS.

These may include:

- Medicine to reduce the risk of fever (such as paracetamol)
- Medicine to reduce the risk of inflammation (corticosteroids)
- Medicine to reduce the risk of an allergic reaction (antihistamines).

You may also be given these medicines for later doses of ELREXFIO based on any symptoms you have. You may also be given additional medicines based on any symptoms you experience or your medical history.

After you receive the first two doses

- Hospitalisation is recommended for 48 hours after you receive the first step-up dose and for 24 hours after you receive the second step-up dose.
- Your doctor will monitor you for side effects for 48 hours after each of your first two doses due to the risk of CRS and ICANS.

If you forget to use ELREXFIO

ELREXFIO should be used regularly at the same time each week up to Week 24, at the same time each fortnight from Week 25, and at the same time every four weeks from Week 49.

If you miss your dose at the usual time, the dose should be administered as soon as possible, and the dosing schedule adjusted as needed to maintain the dose interval.

If you cannot keep your appointment with the doctor, make sure you call your doctor right away so another appointment can be made as soon as possible.

If you use too much ELREXFIO

This medicine will be given by your healthcare professional. In the unlikely event that you are given too much (an overdose) your healthcare professional will check you for side effects.

5. What should I know while using ELREXFIO?

Things you should do

Make sure you follow your doctor's instructions and keep all appointments.

Tell your doctor immediately if you develop any of the signs or symptoms of CRS or neurological problems including ICANS listed below, at any time during your treatment with ELREXFIO.

CRS

Symptoms of CRS may include:

- Fever (38°C or higher)
- Difficulty breathing
- Chills
- Dizziness or light headedness
- Fast heartbeat
- Increased liver enzymes in your blood.

Neurological problems, including ICANS

Symptoms of neurological problems may include:

- Numbness and tingling (feeling like pins and needles)
- Confusion
- Trouble speaking
- Muscle spasms
- Tremor
- Changes in your handwriting
- Problems walking
- Muscle weakness
- Burning, throbbing or stabbing pain.

Infections

Upper respiratory tract infections and pneumonia are the most common infections with ELREXFIO. ELREXFIO can cause bacterial and viral infections, including opportunistic infections, that are severe, life-threatening, or that may lead to death.

- Your doctor will monitor you for symptoms of infection before and during treatment with ELREXFIO.
- Your doctor may prescribe medicines for you to help prevent infections and treat you as needed if you develop an infection during treatment with ELREXFIO.

Decreased white blood cell counts

Decreased white blood cell counts are common with ELREXFIO and can also be severe. Fever sometimes also happens with low white blood cell counts and may be a sign that you have an infection.

- Your doctor will check your blood cell counts before you start and during treatment with ELREXFIO, and treat you as needed.

Your doctor may temporarily or permanently stop ELREXFIO if you have any of the side effects listed above and they are severe.

Tell your healthcare professional if you notice any signs of the above. The symptoms are listed under “Serious side effects” in Section 6. Are there any side effects?

Call your doctor straight away if you:

- Get a fever, chills or any symptom of an infection.

Remind any doctor, dentist or pharmacist you visit that you are using ELREXFIO.

Things you should not do

- Do not give ELREXFIO to anyone else, even if they have the same condition as you.
- Do not use ELREXFIO to treat any other complaints unless your doctor tells you to.
- Do not stop using ELREXFIO without checking with your doctor.

Driving or using machines

Do not drive or operate heavy or potentially dangerous machinery during treatment with ELREXFIO and for 48 hours after each of the 2 doses of ELREXFIO that are part of the 'step-up dosing schedule'.

If you develop new neurological symptoms such as feeling less alert, tiredness, dizziness or confusion while using ELREXFIO do not drive or operate heavy or potentially dangerous machinery until the symptoms go away.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

ELREXFIO is stored and administered by healthcare professionals so it is unlikely that you will store this medicine at home.

ELREXFIO should be stored in a refrigerator (2°C to 8°C) and kept in the original carton in order to protect from light. Do not freeze. Do not shake.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

ELREXFIO will be disposed of appropriately by your healthcare professional.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
Blood related issues: • Bleeding or bruising more easily • Low white blood cell count, red blood cell count or platelet cell count • High liver enzymes • Low potassium and/or phosphate levels **Gastrointestinal issues** • Nausea (feeling sick), diarrhoea or vomiting **Metabolism and nutrition disorders** • Loss of appetite **Skin related issues** • Dry skin or skin rash **Injection site reaction**	**Speak to your doctor if you have any of these side effects and they worry you.**
• Skin rash, itching, hard lumps, swelling, pain, bruising, rash or bleeding at injection site **General disorders and administration site conditions** • Fatigue, tiredness, lack of energy • Headache • Fever • Feeling of weakness in your muscles and pain in your joints	

Serious side effects

Serious side effects	What to do
Allergic type reactions • Chest tightness • Shortness of breath, wheezing or difficulty breathing • Swelling of the face, lips, tongue or other parts of the body • Hives, itching or skin rash. **Immune reaction (CRS)** • Fever, difficulty breathing, chills, dizziness or light-headedness, fast heartbeat, increased liver enzymes in your blood **Neurological problems (including ICANS)** • Nervous system effects such as headache, feeling confused, feeling less alert, having difficulty speaking or writing • Feeling like pins and needles • Muscle spasms and tremors • Burning, throbbing or stabbing pain • Signs and symptoms of a brain infection called progressive multifocal leukoencephalopathy such as weakness or clumsiness, speech difficulties, vision and personality changes **Infection issues** • Signs and symptoms suggestive of an infection	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
or an extreme reaction to an infection (known as sepsis) such as fever, chills, listlessness, paleness • Signs and symptoms of an infection in your chest may also include discomfort in your chest, dizziness, breathlessness, rapid heart rate and weakness • Signs of a urinary tract infection such as wanting to urinate more often and urgently, burning pain when urinating, feeling that the bladder is still full after urinating, urine that is cloudy, very smelly or bloody. • Signs and symptoms of a type of herpes virus called cytomegalovirus that causes a fever, sore throat, swollen glands and feeling tired. **Blood related issues** • Signs and symptoms suggestive of blood abnormalities such as persistent fever, bruising, bleeding very easily, paleness. **Gastrointestinal issues** • Severe diarrhoea	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ELREXFIO contains

Active ingredient (main ingredient)	Elranatamab
Other ingredients (inactive ingredients)	Histidine Histidine hydrochloride monohydrate Disodium edetate Polysorbate 80 Sucrose Water for Injections
Potential allergens	None

Do not use this medicine if you are allergic to any of these ingredients.

ELREXFIO does not contain lactose, gluten, tartrazine or any other azo dyes.

What ELREXFIO looks like

ELREXFIO contains 40 mg/mL elranatamab and is a clear to slightly opalescent, colourless to pale brownish sterile liquid solution.

ELREXFIO 44 mg/1.1 mL Vial

ELREXFIO (elranatamab) 44 mg in 1.1 mL solution for injection vial AUST R 408212

ELREXFIO 76 mg/1.9 mL Vial

ELREXFIO (elranatamab) 76 mg in 1.9 mL solution for injection vial AUST R 408213

Who distributes ELREXFIO

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedical.com.au

This leaflet was prepared in September 2026.

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