**Package leaflet: Information for the user**

**ELREXFIO 40 mg/mL solution for injection**
elranatamab

▼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 are given 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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What ELREXFIO is and what it is used for

ELREXFIO is a cancer medicine that contains the active substance elranatamab. It is used to treat adults with a type of cancer of the bone marrow called multiple myeloma.
It is used by itself for patients whose cancer has returned (relapsed) and stopped responding to previous treatments (refractory), who have had at least three other kinds of treatment and whose cancer has worsened since receiving the last treatment.

**How ELREXFIO works**
ELREXFIO is an antibody, a type of protein, which has been designed to recognise and attach to specific targets in your body. ELREXFIO 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 lymphocytes, a particular kind of white blood cell in your immune system. This medicine works by attaching to these targets and, by doing so, bringing the cancer cells and T cells together. This helps your immune system destroy the multiple myeloma cancer cells.

## 2. What you need to know before you are given ELREXFIO

**You must not be given ELREXFIO**
If you are allergic to elranatamab or any of the other ingredients of this medicine (listed in section 6).
If you are not sure if you are allergic, talk to your doctor or nurse before you are given ELREXFIO.

**Warnings and precautions**
Tell your doctor or nurse about all of your medical conditions before you are given ELREXFIO, including if you have had any recent infections.

**Look out for serious side effects.**

**Tell your doctor or nurse right away if you experience any of the following:**

- Signs of a condition known as 'cytokine release syndrome' (CRS). CRS is a serious immune reaction with symptoms such as fever, difficulty breathing, chills, headache, low blood pressure, fast heartbeat, feeling dizzy, and increased levels of liver enzymes in the blood.
- Effects on your nervous system. Symptoms include feeling confused, feeling less alert, or having difficulty speaking or writing. Some of these may be signs of a serious immune reaction called 'immune effector cell-associated neurotoxicity syndrome' (ICANS).
- Signs and symptoms of an infection such as fever, chills, fatigue, or difficulty breathing.

Tell your doctor or nurse if you notice any signs of the above.

**ELREXFIO and vaccines**
Talk to your doctor or nurse before you are given ELREXFIO if you have had a recent vaccination or are going to have a vaccination.

You should not receive live vaccines within the four weeks before your first dose of ELREXFIO, while you are treated with ELREXFIO, and at least four weeks after stopping treatment with ELREXFIO.

**Tests and checks**
**Before you are given ELREXFIO**, your doctor will check your blood counts for signs of infection. If you have any infection, it will be treated before you start ELREXFIO. Your doctor will also check if you are pregnant or breast-feeding.

**During treatment with ELREXFIO**, your doctor will monitor you for side effects. Your doctor will monitor you for signs and symptoms of CRS and ICANS for 48 hours after each of your first two doses of ELREXFIO. Your doctor will also regularly check your blood counts, as the number of blood cells and other blood components may decrease.

**Children and adolescents**
ELREXFIO is not intended for children or adolescents below 18 years of age. This is because it is not known how the medicine will affect them.

**Other medicines and ELREXFIO**
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines (e.g., cyclosporine, phenytoin, sirolimus, and warfarin). This includes medicines you can get without a prescription, and herbal medicines.

**Pregnancy and breast-feeding**
It is not known if ELREXFIO affects an unborn baby or if it passes into breast milk.

<u>Pregnancy-information for women</u>

ELREXFIO is not recommended during pregnancy.

Tell your doctor or nurse before receiving ELREXFIO if you are pregnant, think you might be pregnant or are planning to have a baby.

If you are able to become pregnant, your doctor should do a pregnancy test before you start treatment.

If you become pregnant while being treated with this medicine, tell your doctor or nurse straight away.

<u>Contraception</u>

If you could become pregnant, you must use effective contraception during treatment and for 6 months after stopping treatment with ELREXFIO.

Breast-feeding

You should not breast-feed during treatment and for 6 months after stopping treatment with ELREXFIO.

**Driving and using machines**
Some people may feel tired, dizzy, or confused while receiving ELREXFIO. Do not drive, use tools, or operate machines until at least 48 hours after each of your 2 step-up doses, and until your symptoms improve, or as instructed by your healthcare professional.

**ELREXFIO contains sodium**
ELREXFIO contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free.'

## 3. How ELREXFIO is given

**How much is given**
You will receive ELREXFIO under the supervision of a healthcare professional experienced in cancer treatment. The recommended dose of ELREXFIO is 76 mg, but the first two doses will be lower.

ELREXFIO is given as follows:
- You will receive a first step-up dose of 12 mg on Day 1 of Week 1.
- You will then receive a second step-up dose of 32 mg on Day 4 of Week 1.
- From Week 2 to Week 24 (Day 1), you will receive a full treatment dose of 76 mg once a week, as long as you are getting benefit from ELREXFIO.
- From Week 25 onwards, your doctor may change your treatment from once a week to once every two weeks, as long as your cancer has responded to ELREXFIO treatment.

You should stay close to a healthcare facility for 48 hours after each of the first two step-up doses in case you have side effects. Your doctor will monitor you for side effects for 48 hours after each of your first two doses.

**How the medicine is given**
ELREXFIO will always be given to you by your doctor or nurse as an injection under your skin (subcutaneous). It is given in the stomach area or thigh.

You may get a reaction at the injection site including, redness of the skin, pain, swelling, bruising, rash, itching, or bleeding. These effects are usually mild and clear up by themselves without the need for any additional treatment.

**Other medicines given during treatment with ELREXFIO**
You will be given medicines one hour before each of your first three doses of ELREXFIO. These help to lower the chance of side effects, such as cytokine release syndrome (see section 4). These medicines may include:
- Medicines to reduce the risk of fever (such as paracetamol)
- Medicines to reduce the risk of inflammation (corticosteroids)
- Medicines to reduce the risk of an allergic reaction (antihistamines, such as diphenhydramine)

You may also be given these medicines for later doses of ELREXFIO based on any symptoms you have after taking ELREXFIO.

You may also be given additional medicines based on any symptoms you experience or your medical history.

**If you are given more ELREXFIO than you should**
This medicine will be given by your doctor or nurse. In the unlikely event that you are given too much (an overdose) your doctor will check you for side effects.

**If you miss your appointment to have ELREXFIO**
It is very important to go to all your appointments to make sure your treatment works. If you miss an appointment, make another one as soon as possible.

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**
Get medical help straight away if you get any of the following serious side effects, which may be severe and can be fatal.

**Very common (may affect more than 1 in 10 people):**
- Cytokine release syndrome, a serious immune reaction that may cause fever, difficulty breathing, chills, dizziness or light-headedness, fast heartbeat, increased liver enzymes in your blood;
- Low levels of neutrophils (a type of white blood cell that fights infection; neutropenia);
- Low levels of antibodies called 'immunoglobulins' in the blood (hypogammaglobulinaemia), which may make infections more likely;
- Infection, which may include fever, chills, fatigue, or shortness of breath.

**Common (may affect up to 1 in 10 people):**
- Immune effector cell-associated neurotoxicity syndrome (ICANS), a serious immune reaction that may cause effects on your nervous system. Some of the symptoms are:
    - Feeling confused
    - Feeling less alert
    - Having difficulty speaking or writing

Tell your doctor right away if you notice any of the above-listed serious side effects.

**Other side effects**
Other side effects are listed below. Tell your doctor or nurse if you get any of these side effects.

**Very common (may affect more than 1 in 10 people):**
- Low levels of red blood cells (anaemia)
- Feeling tired or weak
- Nose and throat infection (upper respiratory tract infection)
- Reactions at or near the injection site, including redness of the skin, itching, swelling, pain, bruising, rash, or bleeding
- Diarrhoea
- Lung infection (pneumonia)
- Low levels of blood platelets (cells that help blood to clot; thrombocytopenia)
- Low levels of a type of lymphocytes, a type of white blood cell (lymphopenia)
- Fever (pyrexia)
- Decreased appetite
- Skin rash
- Dry skin
- Pain in your joints (arthralgia)
- Low levels of potassium in the blood (hypokalaemia)

- Feeling sick (nausea)
- Headache
- Difficulty breathing (dyspnoea)
- Blood poisoning (sepsis)
- Low number of white blood cells (leucopenia)
- Increased level of liver enzymes in the blood (transaminases increased)
- Nerve damage in legs and/or arms that may cause tingling, numbness, pain, or loss of sensation (peripheral neuropathy)
- Infection of the parts of the body that collect and pass out urine (urinary tract infection)

**Common (may affect up to 1 in 10 people):**
- Low level of phosphates in the blood (hypophosphataemia)
- Low number neutrophils in the blood, combined with a fever (febrile neutropenia)

**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 at: 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 ELREXFIO

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

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 label after "EXP". The expiry date refers to the last day of that month.

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

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

The prepared syringe may be stored for 24 hours at up to 30 °C.

Do not use this medicine if you notice discolouration or other visible signs of deterioration.

## 6. Contents of the pack and other information

**What ELREXFIO contains**
- The active substance is elranatamab. ELREXFIO comes in two different package sizes:
    - One 1.1 mL vial contains 44 mg of elranatamab (40 mg/mL).
    - One 1.9 mL vial contains 76 mg of elranatamab (40 mg/mL).

The other ingredients are edetate disodium, L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose, water for injections (see "ELREXFIO contains sodium" in section 2).

**What ELREXFIO looks like and contents of the pack**
ELREXFIO 40 mg/mL solution for injection (injection) is a colourless to pale brown liquid.
ELREXFIO is supplied in two strengths. Each carton pack contains 1 glass vial.

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**Manufacturer**
Pfizer Service Company BV
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For any information about this medicine, please contact:
Medical Information, Pfizer Ltd, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS.
Telephone 01304 616161.

**This leaflet was last revised in 01/2024.**

This medicine has been given 'conditional approval'. This means that there is more evidence to come about this medicine.
The licensing authority will review new information on this medicine at least every year and this leaflet will be updated as necessary.

Ref: EA 1_2

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The following information is intended for healthcare professionals only:

ELREXFIO 40 mg/mL solution for injection is supplied as ready-to-use solution that does not need dilution prior to administration. Do not shake.

ELREXFIO is a clear to slightly opalescent, and colourless to pale brown solution. The solution should not be administered if it is discoloured or contains particulate matter.

Aseptic technique should be used to prepare and administer ELREXFIO.

Preparation instructions

ELREXFIO 40 mg/mL solution for injection vials are for single use only.

ELREXFIO should be prepared following the instructions below (see Table 1) depending on the required dose. It is suggested to use a 44 mg/1.1 mL (40 mg/mL) single dose vial for each one of the step-up doses.

**Table 1. Preparation instructions for ELREXFIO**

| **Required dose** | **Dose volume** |
|---|---|
| 12 mg (Step-up dose 1) | 0.3 mL |
| 32 mg (Step-up dose 2) | 0.8 mL |
| 76 mg (Full treatment dose) | 1.9 mL |

Once punctured, the vial and dosing syringe should be used immediately. If the prepared dosing syringe is not used immediately, store syringe between 2 °C to 30 °C for a maximum of 24 hours.

Administration instructions

ELREXFIO is for subcutaneous injection only and should be administered by a healthcare professional.

The required dose of ELREXFIO should be injected into the subcutaneous tissue of the abdomen (preferred injection site). Alternatively, ELREXFIO may be injected into the subcutaneous tissue of the thigh.

ELREXFIO for subcutaneous injection should not be injected into areas where the skin is red, bruised, tender, hard, or areas where there are scars.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Disposal

The vial and any remaining contents should be discarded after a single use. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.