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Package Leaflet: Information for the user

Elranatamab solution for injection 40 mg/mL

ELDUXIO®

Read all of this leaflet carefully before you start taking 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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ELDUXIO (Elranatamab) is and what it is used for
2. What you need to know before you take ELDUXIO (Elranatamab)
3. How to take ELDUXIO (Elranatamab)
4. Possible side effects
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1. What ELDUXIO (Elranatamab) is and what it is used for

ELDUXIO 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 indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least four prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

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How ELDUXIO (Elranatamab) works

ELDUXIO (Elranatamab) is an antibody, a type of protein which has been designed to recognise and attach to specific targets in your body. ELDUXIO (Elranatamab) 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 cells 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 take ELDUXIO (Elranatamab)

You must not be given ELDUXIO (Elranatamab)

If you are allergic to ELDUXIO (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 ELDUXIO (Elranatamab).

Warnings and precautions

Tell your doctor or nurse about all of your medical conditions before you are given ELDUXIO (Elranatamab), 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, chills, nausea, fast heartbeat, feeling dizzy, and difficulty breathing.
- 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.

ELDUXIO (Elranatamab) and vaccines

Talk to your doctor or nurse before you are given ELDUXIO (Elranatamab) 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 ELDUXIO (Elranatamab) and while you are treated with ELDUXIO (Elranatamab), and at least four weeks after stopping treatment with ELDUXIO (Elranatamab).

Tests and checks

Before you are given ELDUXIO (Elranatamab), your doctor will check your blood counts for signs of infection. If you have any infection, it will be treated before you start ELDUXIO (Elranatamab). Your doctor will also check if you are pregnant or breast-feeding.

During treatment with ELDUXIO (Elranatamab), 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 ELDUXIO (Elranatamab). Your doctor will regularly check your blood counts, as the number of blood cells and other blood components may decrease.

Children and adolescents

ELDUXIO (Elranatamab) 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 ELDUXIO (Elranatamab)

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 ELDUXIO (Elranatamab) affects an unborn baby or if it passes into breast milk.

Pregnancy-information for women

ELDUXIO (Elranatamab) is not recommended during pregnancy.

Tell your doctor or nurse before you are given ELDUXIO (Elranatamab) 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.

Contraception

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

Breast-feeding

You must not breast-feed during treatment and for 6 months after stopping treatment with ELDUXIO (Elranatamab).

Driving and using machines

Some people may feel tired, dizzy, or confused while receiving ELDUXIO (Elranatamab). Do not drive, use tools, or operate machines until at least 48 hours after each of your 2 step-up doses, or as instructed by your healthcare professional.

ELDUXIO (Elranatamab) contains sodium

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

3. How to take ELDUXIO (Elranatamab)**How much is given**

You will receive ELDUXIO (Elranatamab) under the supervision of a healthcare professional. The recommended dose of ELDUXIO (Elranatamab) is 76 mg, but the first two doses will be lower.

ELDUXIO (Elranatamab) 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 ELDUXIO (Elranatamab).
- 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 ELDUXIO (Elranatamab) 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

ELDUXIO (Elranatamab) 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 ELDUXIO (Elranatamab)

You will be given medicines one hour before each of your first three doses of ELDUXIO (Elranatamab). These help to lower the chance of side effects, such as cytokine release syndrome (see section 4). These medicines 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 such as diphenhydramine)

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

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

If you are given more ELDUXIO (Elranatamab) 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 ELDUXIO (Elranatamab)

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 a 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 cells (lymphopenia)
- Fever (pyrexia)
- Decreased appetite
- Skin rash
- Dry skin
- Pain in your joints (arthralgia)
- Low level of potassium in the blood (hypokalaemia)
- Feeling sick (nausea)
- Headache
- Being short of breath (dyspnoea)
- Severe infection throughout the body (sepsis)
- Low number of white blood cells (leucopenia)
- Increased level of liver enzymes in the blood (transaminases increased)
- Nerve damage that may cause tingling, numbness, pain, or loss of pain 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 of neutrophils in the blood, combined with a fever (febrile neutropenia)

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

5. How to store ELDUXIO (Elranatamab)

ELDUXIO (Elranatamab) 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 “Expiry Date”. 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.

Chemical and physical in-use stability has been demonstrated for 24 hours up to 30 °C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 °C to 8 °C, unless preparation has taken place in controlled and validated aseptic conditions.

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

6. Contents of the pack and other information

What ELDUXIO (Elranatamab) contains

- The active substance is Elranatamab. ELDUXIO (Elranatamab) 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 dihydrate, L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose, water for injection (see “ELDUXIO (Elranatamab) contains sodium” in section 2).

What ELDUXIO (ELRANATAMAB) looks like and contents of the pack

ELDUXIO (Elranatamab) is a solution for injection (injection) and is a colourless to pale brown liquid.

Pack sizes:

1.1 mL solution in a vial (Type 1 glass) with a stopper (butyl rubber) and an aluminium seal with a flip-off cap containing 44 mg of elranatamab.

Pack size of 1 vial.

1.9 mL solution in a vial (Type 1 glass) with a stopper (butyl rubber) and an aluminium seal with a flip-off cap containing 76 mg of elranatamab.

Pack size of 1 vial.

All strengths/presentation mentioned in this document may not be marketed.

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