

Treatment Fact Sheet

ELRANATAMAB (ELREXFIO®)

This treatment fact sheet provides information about the myeloma treatment, elranatamab (which is also called by the brand name, Elrexfio®).

Elranatamab is not yet listed on the Pharmaceutical Benefits Scheme (PBS), the government body that subsidises medicines in Australia.

At the moment, elranatamab is available through clinical trials.

When you need a new treatment for myeloma, ask your doctor if a clinical trial with elranatamab – or a clinical trial with another new treatment – may be an option for you.

What is elranatamab?

Elranatamab is a new medicine being used for the treatment of myeloma. It belongs to the group of treatments called immunotherapies, which help the immune system to recognise and kill cancer cells. Elranatamab is a type of immunotherapy called a bispecific antibody. You may also hear it called a bispecific T-cell engager.

How does elranatamab work?

Elranatamab works by recognising and binding to proteins on two different types of cells and then bringing the cells together:

- One part of elranatamab recognises and binds to a protein on the surface of myeloma cells called B-cell maturation antigen or BCMA.
- BCMA is mostly found on myeloma cells and in small amounts on healthy cells. This means that elranatamab can effectively target myeloma cells, while having fewer effects on healthy cells.
- The other part of elranatamab binds to a protein on healthy immune T cells called CD3.
- Elranatamab then forms a link between the myeloma cells and T cells and directs the T cells to kill the myeloma cells.

How is Elranatamab given?

Elranatamab is given by a member of your treating team as an injection into the skin (subcutaneously), usually into your stomach or thigh using a 'step-up' dosing schedule. This means you will start with a low dose that will gradually be increased. Gradually stepping up your dose like this helps to control the rate of myeloma cell death and reduces the effect of cytokine release syndrome (CRS). You can read more about CRS below.

Step-up dosing schedule:

- The first dose is 12mg and will be given on day one of the first cycle.
- The second dose is 32mg and will be given on day four of the first cycle.
- The 'treatment dose' is 76mg and will be given on day eight of the first cycle.
- You will then continue to have the treatment dose once a week for 24 weeks.
- After 24 weeks, the schedule changes to receiving elranatamab every two weeks for as long as you are getting benefit from elranatamab.

Medicines given with elranatamab

To help reduce the chance of side effects, you may also be given medicines before each of your first three injections of elranatamab. These medicines may include an antihistamine, steroid and paracetamol. Your treating team will then decide if you need to have these medicines for later doses of elranatamab. This will depend on any side effects you experience and your medical history.

How will I know if elranatamab is working?

When having treatment with elranatamab, you may notice fewer symptoms caused by your myeloma, and this may give you an improved quality of life. Your doctor will also order tests at the start of each treatment cycle (usually every 4 weeks) to see how you are responding to treatment. These tests vary from person to person, but generally include blood and/or urine tests and occasional scans or bone marrow biopsies.

What are the possible side effects of elranatamab?

All medicines, including elranatamab, have possible side effects. These can vary a lot from person to person and may be mild or more serious.

Knowing about the possible side effects and talking openly about these with your treating team can help you to plan together and quickly get on top of any that you experience.

In the next pages, we have included information about some of the more common side effects as well as practical tips that can help to prevent and manage these. Your treating team will explain more about these too.

Cytokine release syndrome (CRS)

Many people treated with elranatamab experience some degree of cytokine release syndrome (CRS). CRS happens when the treatment causes a body-wide inflammatory response where large numbers of proteins, called cytokines, are released. This is sometimes called a 'cytokine storm'.

The symptoms and severity of CRS can vary between different people and may include:

- fever
- headache
- low blood pressure
- rapid breathing
- rapid heartbeat
- low oxygen level
- fatigue
- muscle and/or joint pain
- nausea and vomiting.

CRS usually occurs in the first cycle and symptoms can be experienced up to six days after the dose has been administered.

In most people who experience CRS, the symptoms are mild to moderate and will settle with simple treatments, but it's important to know that CRS can be very severe and life-threatening. Always let your treating team know if you experience any of the symptoms listed above.

What can help?

- Ask your hospital for a patient card with information about CRS. You need to carry this card with you at all times while you are on treatment.
- You will be monitored closely by your treating team for any signs and symptoms of CRS by regularly checking your vital signs.
- Remember to let your treating team know about any symptoms you experience as soon as you notice them.
- Depending on where you live, you may be asked to stay closer to the place where you received your treatment for at least 2 days for daily monitoring. You should do this for your first three doses (usually two step-up doses and your first treatment dose).
- Symptoms of CRS usually get better with simple treatments, such as paracetamol to bring down fever.
- More severe symptoms may be treated with a medicine called tocilizumab, which is given as an infusion into a vein over 1 hour. Tocilizumab reduces the inflammatory response caused by the cytokines without affecting how the treatment works.
- Some people may only need one dose of tocilizumab, while other people may need more doses. If you need more than one dose of tocilizumab, you will usually be given a small dose of a steroid like dexamethasone to help further reduce cytokine levels.

Neurotoxicity

Elranatamab can have effects on your nervous system, causing a type of neurotoxicity called immune-effector cell-associated neurotoxicity syndrome (ICANS).

This side effect is less common than CRS. We don't yet understand as much about neurotoxicity and why it affects some people having elranatamab treatment. The symptoms and severity of neurotoxicity can vary between different people and may include:

- headaches
- confusion
- feeling less alert
- tremors (shaking)
- loss of balance
- agitation
- speaking slowly
- difficulty writing, reading or understanding words.
- Neurotoxicity usually occurs later than CRS, but in some cases, they can happen at the same time.

What can help?

- You will be monitored closely by your treating team for any signs and symptoms of neurotoxicity using a tool that checks your ability to name objects and follow directions, as well as your orientation, concentration and handwriting.
- Remember to let your treating team know about any symptoms you experience as soon as you notice them.
- Neurotoxicity is usually treated with the steroid, dexamethasone. Symptoms usually get better over several days.

Increased risk of infection

Elranatamab can cause a decrease in white blood cells that form part of your body's immune system to help fight infections. A low white blood cell count increases the risk of developing an infection.

Elranatamab can also cause a decrease in normal antibody levels which further reduces the body's ability to fight infection.

What can help?

- Take extra care to prevent infections, such as washing or sanitising your hands regularly and staying away from other people with coughs, colds or other infections.
- Your doctor will prescribe medications to take to help protect against infections.
- Vaccines can also help protect against infections. Talk to your doctor about which vaccines are recommended for you. It's important to note that 'live' vaccines are not recommended for people with myeloma, only 'inactive' vaccines are safe.
- If your white cell count stays low, you may need to have daily injections of granulocyte-colony stimulating factor (G-CSF) to increase your white blood cell count.
- If you do develop an infection, your doctor may prescribe antibiotics.
- If you are experiencing recurrent infections, your doctor may recommend regular immunoglobulin replacement therapy either as an intravenous or subcutaneous injection.

Having a temperature of 38°C or higher is a common sign of infection.

Always get urgent medical attention for a temperature of 38°C or more.

Low blood counts

Elranatamab can also cause a decrease in the number of platelets and red blood cells in the blood.

Low platelet count (thrombocytopenia)

A low platelet count is the most common side effect on the blood from elranatamab.

Platelets, which are also called thrombocytes, help your blood to clot. Having a low platelet count can result in bruising and bleeding.

What can help?

- Your doctor will monitor your platelet count before and during treatment.
- If your platelet count becomes too low, you may need a short break from treatment. If your platelet count is consistently low, you may need a change in dose of elranatamab.
- If your platelets need help returning to normal, you may need a platelet infusion.

Low red blood cell count

Red blood cells contain haemoglobin, which contain iron and transport oxygen in your body. A low red blood cell count may cause anaemia, tiredness, and make you short of breath.

What can help?

- If you become anaemic, you may need a blood transfusion.

Fatigue

Fatigue is very common with any cancer treatment. It can also be difficult to tell the difference between fatigue caused by a treatment or by myeloma itself.

What can help?

- You may be able to help reduce fatigue by:
 - eating a healthy diet
 - keeping up your fluids
 - enjoying gentle, regular exercise
 - having a regular sleep schedule where you go to bed and get up at the same time each day.

Talk to your treating team about any fatigue you are feeling. Your team will keep an eye on your red blood cell count, talk to you about other medicines or issues that may be adding to your fatigue, and may prescribe medicine to help reduce fatigue.

Myeloma Australia's [Fatigue and myeloma](#) information sheet includes more practical tips to help you manage cancer-related fatigue.

Effects on fertility, pregnancy and breastfeeding

There is little known about the effects of elranatamab on fertility in women and men.

Elranatamab may cause harm to an unborn child, and cause serious side effects in a breastfed baby:

- Women must use effective contraception during treatment and for 5 months after finishing treatment.
- Men must use effective contraception during treatment and for 3 months after finishing treatment.
- Breastfeeding is not recommended during treatment with elranatamab and for at least 5 months after the last dose.
- If you are planning to have children in the future, your doctor can advise you on fertility preservation options.

Questions to ask my treating team

Here are some suggested questions you might like to ask your treating team to help you understand more about what to expect when receiving elranatamab. Remember, there is no such thing as a silly question!

- How will I know if the treatment is working?
- What should I do if I have a new or worsening side effect or symptom while on treatment?
- How long do I need to stay close to my treatment centre after each dose of elranatamab?
- Can you tell me more about cytokine release syndrome (CRS) and neurotoxicity?
- What should I do if I am already taking or need to start taking any other medicines?

The information in this fact sheet is not intended to replace medical care or the advice of your treating team.

Please talk to your doctor if you have any questions about your diagnosis or treatment. Your doctor can answer your questions, talk with you about your treatment goals, and provide you with extra support.

**For further information please contact our Myeloma
Support Nurses on our toll free Support Line:
1800 MYELOMA (1800 693 566)
or visit our website: www.myeloma.org.au**