Elotuzumab (Empliciti®)

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

Elotuzumab has recently been listed on the Pharmaceutical Benefits Scheme (PBS), where medicines in Australia are subsidised by the government and available at the cost of a standard prescription, making the treatment much more affordable.

The treatment is available for people whose myeloma has progressed after having at least one previous treatment.

Elotuzumab is always used in combination with the immunomodulatory medicine, lenalidomide (Revlimid®) and the steroid, dexamethasone. This combination of treatments is often called ERd.

When you need a new treatment for myeloma, ask your doctor if ERd may be an option for you.

What is elotuzumab and how does it work?

Elotuzumab is a medicine used to treat myeloma. It belongs to the class of medicines called monoclonal antibodies.

Monoclonal antibodies are engineered in the laboratory to copy the process that our immune system usually uses to recognise and fight foreign substances. In this case, elotuzumab has been made to find a protein called SLAMF7.

Large amounts of SLAMF7 are present on the surface of myeloma cells, and also on immune system cells called natural killer (NK) cells.

When elotuzumab attaches to SLAMF7, it stimulates your immune system to recognise and kill the myeloma cells.

How is elotuzumab given?

Elotuzumab is given by your treating team as a slow drip into a vein – usually into your hand, arm or an IV port. This is called having an intravenous or IV infusion.

The length of each elotuzumab infusion will depend on how much you weigh and how many times you have already received the medicine.

Before each infusion, your treating team will give you medicines (called premedications or premeds) to help reduce the chance of an infusion reaction.

If you do have an infusion reaction, or a reaction becomes worse, it may take more time to have your infusion.

Your elotuzumab treatment cycle

Elotuzumab treatment is divided into cycles, which are each 28 days (4 weeks) long. Each cycle includes the days you are receiving treatment as well as rest days with no treatment, which are at the end of each cycle.

Your doctor will work out the right dosage and number of cycles you will receive.

The treatment is usually given:

- once a week for cycles 1 and 2
- once every 2 weeks for cycles 3 and after.

During each cycle, you will also take lenalidomide and dexamethasone orally (by mouth).

Before each infusion, your treating team will give you medicines, called premedications or 'pre-meds', to help reduce the chance of an infusion reaction.

The following tables help to show when elotuzumab and your other medicines will be given.

Cycles 1 & 2 (28 days each)

Day 1	Day 8	Day 15	Day 22	Days 23-28
Premedication	Premedication	Premedication	Premedication	Rest period
Elotuzumab infusion	Elotuzumab infusion	Elotuzumab infusion	Elotuzumab infusion	
	Oral lenalidomide Days 1–2			

^{*}Please note schedule may vary between institutions

Cycles 3 and onwards (28 days each)

*Please note schedule may vary between institutions

Day 1		Day 15		Days 23-28
Premedication		Premedication		Rest period
Elotuzumab infusion		Elotuzumab infusion		
(Oral lenalidomide Days 1–2			

How will I know if elotuzumab with lenalidomide and dexamethasone (ERd) is working?

When having treatment with ERd, 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 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 ERd?

All medicines, including elotuzumab, when used with lenalidomide and dexamethasone, 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. Your team will explain more about the more common side effects.

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

You should also read the Lenalidomide and Steroids treatment fact sheets to learn more about the side effects of these treatments.

It is very important to quickly let your treating team know about any side effects that you have while being treated with ERd.

Infusion-related or allergic reactions

Before each elotuzumab infusion, your treating team will give you medicines to reduce the chance of having an infusion-related reaction.

It's helpful to know that if you do have a reaction, they are usually very mild and nearly all reactions can be managed well.

Let your treating team know straight away if you notice any of these signs and symptoms while you are having an infusion or within 24 hours after your infusion:

- fever
- chills
- rash
- chest pain
- trouble breathing
- dizziness
- · light-headedness.

What can help?

- If you do have a reaction, your infusion will be stopped until your symptoms have gone away. Your doctor may give you some medicine to help with the symptoms too.
- Usually, you will be able to slowly finish your infusion once your symptoms have gone.

Risk of infections

In the largest clinical trial, about 8 out of 10 people receiving ERd experienced infections and some of these can be serious.

It is important to let your treating team know straight away if you develop any symptoms of an infection – these may include:

- fever
- flu-like symptoms
- cough
- · shortness of breath
- burning with urination
- · painful skin rash.

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.
- If your white cell count is low, you may need to have an injection
 of granulocyte-colony stimulating factor (G-CSF) to increase your
 white blood cell count. Your doctor will also prescribe medicine to
 help prevent infections.
- If you do develop an infection, your doctor may prescribe antibiotics.

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.

Fatigue

About 6 in 10 people having ERd treatment experience fatigue.

What can help?

- You may be able to help reduce fatigue by:
 - o Eating a healthy diet
 - o Keeping up your fluids
 - o 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.

Diarrhoea

About 5 in 10 people having ERd treatment experience diarrhoea, and is usually mild and manageable.

What can help?

- If diarrhoea becomes a problem, ask your treating team about simple treatments that can help.
- Make sure you are drinking 2 litres (about 8 glasses) of fluids a day to help prevent dehydration. Fluids can include water, ice chips or ice blocks, rehydration drinks and other clear drinks.

Constipation

About 3–4 in 10 people having ERd treatment experience constipation.

What can help?

- Fibre in your diet absorbs water, helping to make bowel movements softer, bulkier and easier. Eat a varied diet with plenty of vegetables, fruit, legumes and wholegrains, which are high in fibre.
- Drinking plenty of fluids helps the fibre to work. Aim for about 8 glasses of water a day.
- Regular, gentle exercise keeps your bowels more active to help move things along.
- Ask your treating team to recommend a suitable laxative if constipation continues to be a problem.

Risk of developing new cancers

There is a slight risk of developing new cancers after having ERd treatment. Please talk with your doctor if you have any concerns about this.

Liver problems

Elotuzumab may cause liver problems. Your doctor will do blood tests to check your liver during treatment.

Let your treating team know if you have any signs or symptoms of liver problems, which can include:

- tiredness
- weakness
- loss of appetite
- yellowing of your skin or eyes
- changed colour of your bowel motions
- · confusion
- swelling of your stomach area.

Use in pregnancy and breastfeeding

Elotuzumab treatment is given with lenalidomide and dexamethasone, which are known to be harmful to an unborn baby.

When you are having this treatment combination, you must follow the pregnancy prevention program for lenalidomide.

Your doctor can advise on fertility preservation options if you are planning to have children in the future.

This combination of treatments is not recommended while breastfeeding, so please talk to your doctor if you are breastfeeding or planning to breastfeed.

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 with your ERd treatment.

- How long will I continue treatment with ERd??
- How often will I need to have blood tests during treatment?
- Will my dose be changed throughout treatment?
- What should I do if I have a new or worsening side effect or symptom while on treatment?
- 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 a list of references used to develop this treatment fact sheet, please email: nurses@myeloma.org.au

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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