EMPLICITI®

(em-pli-see-tee)

Elotuzumab (elo tu zu mab)

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking EMPLICITI. This leaflet answers some common questions about EMPLICITI.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking EMPLICITI against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What EMPLICITI is used for

EMPLICITI contains the active substance elotuzumab, which is a monoclonal antibody, a type of protein designed to recognise and attach to a specific target substance in the body.

Elotuzumab attaches to a target protein called Signaling Lymphocyte Activation Molecule Family member 7 (SLAMF7). SLAMF7 is found in large amounts on the surface of some cancer cells (multiple myeloma cells) and on certain cells of your immune system (natural killer cells).

When elotuzumab binds to SLAMF7 it stimulates your immune system to attack and destroy the multiple myeloma cells.

EMPLICITI is used to treat multiple myeloma (a cancer of the bone marrow) in adults in combination with other medicines.

Multiple myeloma is a cancer of a type of white blood cell called plasma cells. These cells divide out of control and collect in the bone marrow. This results in damage to the bones and kidneys.

EMPLICITI is used when you have already had one or more other types of treatment before.

EMPLICITI is not recommended for use in children and people under 18 years.

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

EMPLICITI is not addictive. This medicine is available only with a doctor's prescription.

Before you are given EMPLICITI

It is important that you read the information below and talk to your doctor or nurse before you are given EMPLICITI.

You should not be given EMPLICITI

If you are allergic (hypersensitive) to elotuzumab or to any other ingredients in the formulation listed at the end of this leaflet.

Some of the 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.

Using other medicines

EMPLICITI is used in combination with lenalidomide and dexamethasone; it is important that you read the Consumer Medicine Information for these medicinal products.

You should not be given this medicine after the expiry date, which is printed next to EXP on the vial label and carton.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given EMPLICITI

Tell your doctor if you are pregnant or intend to become pregnant.
You should not use EMPLICITI if you are pregnant, unless your doctor specifically recommends it. The effects of EMPLICITI in pregnant women or its possible harm to an unborn baby are unknown.

You must use effective contraception while you are being treated with EMPLICITI.

If you are pregnant, think you may be pregnant, or planning to become pregnant while using EMPLICITI, ask your doctor for advice before taking EMPLICITI.

EMPLICITI is used in combination with lenalidomide and dexamethasone which are medicinal products expected to be harmful to an unborn baby.

When EMPLICITI is used in combination with lenalidomide, you must follow the pregnancy prevention programme for lenalidomide.

Tell your doctor if you are breast-feeding or plan to breast-feed.
It is not known, whether elotuzumab gets into breast milk. A risk to the breast-fed infant cannot be excluded. Ask your doctor if you can breast-feed during or after treatment with EMPLICITI.

If you have not told your doctor about any of the above, tell them before you use EMPLICITI.

Driving and using machines

EMPLICITI is unlikely to affect your ability to drive or use machines. However, if you get an infusion reaction, do not drive, cycle or use machines until the reaction stops.

Important information about some of the ingredients of EMPLICITI

Tell your doctor if you are on a low-sodium (low-salt) diet before you are given EMPLICITI. It contains 0.13 mg sodium per 10 mg elotuzumab.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.
EMPLICITI and other medicines may affect each other.

It is important that you tell your doctor about the medicines you are taking, even if they are not listed in this leaflet.

Your doctor will be able to provide you with more information than is contained within this leaflet on the medicines you need to be careful with, or should avoid while being given EMPLICITI.

How EMPLICITI is given

You will receive EMPLICITI by infusion under the supervision of an experienced healthcare professional. It will be given into a vein (intravenously) as a drip (infusion) over several hours.

The amount of EMPLICITI you will be given will be calculated based on your body weight.

Before you are given the EMPLICITI infusion you must receive the following medicines to help reduce any possible infusion reactions:

- medicines to reduce an allergic reaction (antihistamines)
- medicines to reduce inflammation (dexamethasone)
- medicines to reduce pain and fever (paracetamol).

How much will you be given

You will be given EMPLICITI in treatment cycles in combination with lenalidomide and dexamethasone.

The recommended dose is 10 mg of elotuzumab per kilogram of your body weight.

The frequency in combination with the other medicines is given below.

When EMPLICITI is given together with lenalidomide and dexamethasone, you will receive EMPLICITI intravenously as a 28-day (4-week) treatment cycle at the recommended dose and schedule as follows:

- EMPLICITI: every week (days 1, 8, 15, and 22) for the first 2 cycles and every 2 weeks (day 1 and 15) thereafter.
- Lenalidomide: 25 mg (or as specified by your doctor) given orally once daily for the first 3 weeks of each cycle (at least 2 hours after EMPLICITI infusion when on the same day).
- Dexamethasone is given every week (days 1, 8, 15, and 22) of each cycle as follows:
  - 28 mg orally (between 3 and 24 hours before EMPLICITI infusion) and 8 mg intravenously (45-90 minutes before EMPLICITI infusion) on days with EMPLICITI infusion.
  - 40 mg on days without EMPLICITI infusion.

How long will you be treated

Your doctor will continue to treat you with EMPLICITI until your disease progresses or unacceptable toxicity occurs.

If you miss a dose

EMPLICITI is used in combination with other multiple myeloma medicines. If any medicine in the regimen is delayed, interrupted, or discontinued, your doctor will decide how your treatment should be continued.

If you are given too much (overdose)

As EMPLICITI will be given to you by a healthcare professional, it is unlikely you will be given too much. In the unlikely case of an overdose, your doctor will monitor you for side effects.

If you stop using EMPLICITI

Stopping your treatment may stop the effect of the medicine. Do not stop treatment with EMPLICITI unless you have discussed this with your doctor.

If you have any further questions on the use of this medicine, ask your doctor.

While you are being treated with EMPLICITI

Things you must do

Tell your doctor or nurse immediately if you get any of the infusion reactions listed below.

- Fever
- Chills
- High blood pressure.

Other symptoms may occur as well.

These side effects mostly occur during or after the infusion of the first dose. You will be monitored for signs of such side effects during and after the infusion.

Depending on the seriousness of the infusion reactions:

- You may require additional treatment to prevent complications and reduce your symptoms, or your infusion may be interrupted.
- When the symptoms go away or improve, the infusion can be continued on a lower infusion rate and gradually increased if the symptoms do not recur.
- Your doctor may decide not to continue with EMPLICITI treatment if you have a strong infusion reaction.

Before each infusion of EMPLICITI, you will be given medicines to avoid infusion.

You must read the Consumer Medicine Information for all medicines used in combination with EMPLICITI for information related to these medicines before starting treatment with EMPLICITI.

When lenalidomide is used, particular attention to pregnancy testing and prevention requirements is needed.

- **Infections**
  People with multiple myeloma who receive EMPLICITI with lenalidomide and dexamethasone may develop infections that can be serious.
  Tell your doctor right away if you have any signs and symptoms of an infection, including:
  - fever
  - shortness of breath
  - flu-like symptoms
  - burning with urination
  - cough
  - a painful skin rash.
- **Risk of new cancers (malignancies)**
  People with multiple myeloma who receive EMPLICITI with lenalidomide and dexamethasone have a risk of developing new cancers.
  Talk with your doctor about your risk of developing new cancers if you receive EMPLICITI. Your doctor will check you for new cancers during your treatment with EMPLICITI.
- **Liver problems**
  EMPLICITI may cause liver problems. Your doctor will do blood tests to check your liver during treatment with EMPLICITI.
  Tell your doctor if you have signs and symptoms of liver problems, including:
  - tiredness
  - weakness
  - loss of appetite
  - yellowing of your skin or eyes
  - colour changes in your stools
  - confusion
  - swelling of the stomach area.

Possible side effects

Like all medicines, EMPLICITI can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of your treatment.

It is important that you tell your doctor or nurse immediately if you have, or develop, any of the symptoms listed below.

- **Infusion reactions.**
  EMPLICITI has been associated with infusion reactions. Typical symptoms associated with infusion reactions include:
  - Fever
  - Chills
  - High blood pressure.

Your doctor may consider reducing the infusion rate or interrupting the infusion of EMPLICITI to manage these symptoms.

The following side effects have been reported in clinical trials:

Very common side effects (affects more than 1 in 10 people):

- Weight decrease
- Low white blood cell count
- Cough.

Tell your doctor immediately if you get any of these side effects. Do not try to treat your symptoms with other medicines.

Common side effects (affects up to 1 in 10 people):

- Chest pain
- Night sweats
- Mood changes
- Decreased feeling of sensitivity, especially in the skin
- Painful skin rash with blisters (shingles, herpes zoster)
- Allergic reactions (hypersensitivity).

Tell your doctor immediately if you get any of these side effects. Do not try to treat your symptoms with other medicines.

This is not a complete list of side effects, other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects. You may not experience any of them or only some of them.

Ask your doctor to answer any questions you may have.

Product description

What it looks like

Powder for intravenous infusion

EMPLICITI is provided as a sterile white to off-white powder.

EMPLICITI is available in packs of 1 vial.

Ingredients

- The active substance is elotuzumab.
- Each single use 300 mg vial contains 340 mg Elotuzumab.
- Each single use 400 mg vial contains 440 mg of Elotuzumab.
- After reconstitution, each mL of concentrate contains 25 mg of elotuzumab.

Other ingredients are include:

- Each single use 300 mg vial contains 16.6 mg Sodium citrate, 2.44 mg of citric acid monohydrate, 510 mg sucrose, 3.40 mg Polysorbate 80.
- Each single use 400 mg vial Sodium citrate, 3.17 mg of citric acid monohydrate, 660 mg sucrose, 4.40 mg Polysorbate 80.

Storage

EMPLICITI lyophilized powder must be refrigerated at 2°C - 8°C. Do not freeze or shake.

EMPLICITI should be stored in the original package in order to protect from light.

EMPLICITI contains no microbial agent. EMPLICITI is for single use only. Discard any residue.

Registration Numbers

EMPLICITI elotuzumab 300 mg lyophilized powder for IV infusion vial AUST R 260052.

EMPLICITI elotuzumab 400 mg lyophilized powder for IV infusion vial AUST R 260055.

Sponsored by

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