

EMPLICITI®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor, nurse or pharmacist.

1. Why am I given EMLICITI?

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

For more information, see Section [1. Why am I given EMLICITI?](#) in the full CMI.

2. What should I know before I am given EMLICITI?

Do not use if you have ever had an allergic reaction to elotuzumab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given EMPLICITI?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EMPLICITI and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given EMPLICITI?

- 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

More instructions can be found in Section [4. How am I given EMPLICITI?](#) in the full CMI.

5. What should I know while receiving EMPLICITI?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, nurses and pharmacist who are treating you that you are being given EMPLICITI.
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- Tell your doctor or nurse immediately if you get any of the infusion reactions, including fever, chills, high blood pressure.
- Tell your doctor right away if you have any signs and symptoms of an infection, including fever, shortness of breath, flu-like symptoms, pain or burning when you urinate, cough, a painful skin rash.
- People with multiple myeloma who receive EMPLICITI with lenalidomide and dexamethasone have a risk of developing new cancers. Talk to 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.

	<ul style="list-style-type: none"> • 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.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> • 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.

For more information, see Section [5. What should I know while receiving EMPLICITI?](#) in the full CMI.

6. Are there any side effects?

Serious side effects include infusion reactions. Common side effects include weight decrease, low white blood cell count, cough. Very common side effects include 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).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

EMPLICITI[®] (em-pli-see-tee)

Active ingredient: *elotuzumab* (elo-tu-zu-mab)

Consumer Medicine Information (CMI)

This leaflet provides important information about using EMPLICITI. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about using EMPLICITI.**

Where to find information in this leaflet:

- [1. Why am I given EMPLICITI?](#)
- [2. What should I know before I am given EMPLICITI?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given EMPLICITI?](#)
- [5. What should I know while receiving EMPLICITI?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I given EMPLICITI?

EMPLICITI contains the active ingredient elotuzumab. EMPLICITI 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.

2. What should I know before I am given EMPLICITI?

Warnings

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

Do not use EMPLICITI if:

- you are allergic to elotuzumab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

Using other medicines

- **EMPLICITI is used in combination with lenalidomide and dexamethasone. 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.

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

3. What if I am taking other medicines?

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy 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.

4. How am I given EMPLICITI?

How is EMPLICITI 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 as follows:

- In cycles 1 and 2: 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 (days 1, 8, 15 and 22)
- In cycles 3 and above: 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 (days 1 and 15). 40 mg orally on days without EMPLICITI infusion (days 8 and 22).

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 EMPLICITI

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.

5. What should I know while receiving EMPLICITI?

Things you should do

Remind any doctor, dentist, nurses and pharmacist who are treating you that you are being given EMPLICITI.

Call your doctor if you experience the following:

Infusion Reactions

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

- Fever
- Chills
- High blood pressure

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 reactions.

Infections

Tell your doctor right away if you have any signs and symptoms of an infection, including:

- Fever
- Shortness of breath
- Flu-like symptoms
- Pain or burning when you urinate
- Cough
- A painful skin rash

People with multiple myeloma who receive EMPLICITI with lenalidomide and dexamethasone may develop infections that can be serious.

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

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how EMPLICITI affects you.

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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
Infusion reactions: <ul style="list-style-type: none">• Fever• Chills• High blood pressure	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Other side effects

Other side effects	What to do
<p>Very Common side effects</p> <ul style="list-style-type: none">• Weight decrease• Low white blood cell count• Cough <p>Common side effects</p> <ul style="list-style-type: none">• 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)	<p>Tell your doctor immediately if you have any of these side effects. Do not try to treat your symptoms with other medicines.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What EMPLICITI contains

Active ingredient (main ingredient)	elotuzumab
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">● sodium citrate dihydrate● citric acid monohydrate● sucrose● polysorbate 80

Do not take this medicine if you are allergic to any of these ingredients.

What EMPLICITI looks like

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

EMPLICITI is available in packs of 1 vial.

Registration Numbers

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

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

Who distributes EMPLICITI

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave,

Victoria 3170, Australia.

Toll free number: 1800 067 567

Email: MedInfo.Australia@bms.com

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