

Patient Information
EMPLICITI® (em-plis-city)
(elotuzumab)
for injection

EMPLICITI is used with other prescription medicines called REVLIMID® (lenalidomide) and dexamethasone or POMALYST® (pomalidomide) and dexamethasone. **Read the Medication Guide that comes with REVLIMID if used with REVLIMID and POMALYST if used with POMALYST.** You can ask your healthcare provider or pharmacist for information about dexamethasone.

What is EMPLICITI?

EMPLICITI is a prescription medicine used to treat:

- multiple myeloma in combination with the medicines REVLIMID (lenalidomide) and dexamethasone in adults who have received one to three prior treatments for their multiple myeloma.
- multiple myeloma in combination with the medicines POMALYST (pomalidomide) and dexamethasone in adults who have received at least two prior treatments including REVLIMID (lenalidomide) and a proteasome inhibitor.

It is not known if EMPLICITI is safe and effective in children.

Before you receive EMPLICITI, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection
- are pregnant or plan to become pregnant. It is not known if EMPLICITI may harm your unborn baby. However, REVLIMID and POMALYST may cause birth defects or death of an unborn baby.
 - **Before receiving EMPLICITI with REVLIMID and dexamethasone, or EMPLICITI with POMALYST and dexamethasone, females and males must agree to the instructions in the REVLIMID REMS® program for the use of EMPLICITI in combination with REVLIMID and dexamethasone and the POMALYST REMS® program for the use of EMPLICITI in combination with POMALYST and dexamethasone.**
 - **The REVLIMID REMS and POMALYST REMS programs have specific requirements about birth control (contraception), pregnancy testing, blood donation, and sperm donation that you need to know. Talk to your healthcare provider to learn more about REVLIMID or POMALYST.**
- are breastfeeding or plan to breastfeed. It is not known if EMPLICITI passes into breast milk. You should not breastfeed during treatment with EMPLICITI and REVLIMID and dexamethasone or EMPLICITI and POMALYST and dexamethasone.
- **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive EMPLICITI?

- EMPLICITI will be given to you by intravenous (IV) infusion into your vein.
- Your EMPLICITI treatment schedule is divided into cycles that are 28 days (4 weeks) long. A cycle includes the number of days you are on treatment and also the time you spend resting in between treatments.
- **EMPLICITI with REVLIMID and dexamethasone is usually given as follows:**
 - Cycles 1 and 2 (28 days per cycle), you will receive EMPLICITI one time every week.
 - Cycles 3 and up (28 days per cycle), you will receive EMPLICITI one time every 2 weeks.
- **EMPLICITI with POMALYST and dexamethasone is usually given as follows:**
 - Cycle 1 and 2 (28 days per cycle), you will receive EMPLICITI one time every week.
 - Cycle 3 and up (28 days per cycle), you will receive EMPLICITI one time every 4 weeks.
- Your healthcare provider will decide how many treatments you will receive.
- Before every EMPLICITI infusion, you will receive medicines to help reduce the risk of infusion reactions.
- If you miss any appointments call your healthcare provider as soon as possible.

What are the possible side effects of EMPLICITI?

EMPLICITI may cause serious side effects, including:

- **Infusion reactions.** Infusion reactions can happen during your infusion or within 24 hours after your infusion of EMPLICITI. Your healthcare provider will give you medicines before each infusion of EMPLICITI to help reduce the risk of an infusion reaction.
If you have an infusion reaction while receiving EMPLICITI, your healthcare provider will slow or stop your infusion and treat your reaction. If you have a severe infusion reaction, your healthcare provider may stop your treatment completely. Tell your healthcare provider or get medical help right away if you have any of these symptoms after your infusion with EMPLICITI:
 - fever
 - chills
 - rash
 - chest pain
 - trouble breathing
 - dizziness
 - light-headedness
- **Infections.** People with multiple myeloma who receive EMPLICITI with REVLIMID and dexamethasone or EMPLICITI with POMALYST and dexamethasone may develop infections that can be serious. Tell your healthcare provider right away if you have any signs and symptoms of an infection, including:
 - fever
 - flu-like symptoms
 - cough
 - shortness of breath
 - burning with urination
 - a painful skin rash
- **Risk of new cancers (malignancies).** People with multiple myeloma who receive EMPLICITI with REVLIMID and dexamethasone or EMPLICITI with POMALYST and dexamethasone have a risk of developing new cancers. Talk with your healthcare provider about your risk of developing new cancers if you receive EMPLICITI. Your healthcare provider will check you for new cancers during your treatment with EMPLICITI.
- **Liver problems.** EMPLICITI may cause liver problems. Your healthcare provider will do blood tests to check your liver during treatment with EMPLICITI. Tell your healthcare provider if you have signs and symptoms of liver problems, including: tiredness, weakness, loss of appetite, yellowing of your skin or eyes, color changes in your stools, confusion, or swelling of the stomach area.

The most common side effects of EMPLICITI when used with REVLIMID and dexamethasone include:

- fatigue
- diarrhea
- fever
- constipation
- cough
- numbness, weakness, tingling, or burning pain in your arms or legs
- sore throat or runny nose
- upper respiratory tract infection
- decreased appetite
- pneumonia

The most common side effects of EMPLICITI when used with POMALYST and dexamethasone include:

- constipation
- high blood sugar

These are not all of the possible side effects of EMPLICITI.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Bristol-Myers Squibb at 1-800-721-5072.

General information about the safe and effective use of EMPLICITI

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.

You can ask your pharmacist or healthcare provider for information about EMPLICITI that is written for health professionals.

What are the ingredients of EMPLICITI?

Active ingredient: elotuzumab

Inactive ingredients: citric acid monohydrate, polysorbate 80, sodium citrate, sucrose

For more information, call 1-844-EMPLICITI (844-367-5424) or visit EMPLICITI.com.

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Manufactured by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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