

PATIENT INFORMATION
EVOMELA (ev-o-meh-lah)
(melphalan) for injection, for intravenous use

What is Evomela?

Evomela is a prescription medicine used in people with a type of cancer called multiple myeloma before receiving a stem cell transplant (conditioning treatment).

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

Do not receive Evomela if you are allergic to melphalan or any of the ingredients in Evomela. See the end of this leaflet for a complete list of ingredients in Evomela.

Before receiving Evomela, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection
- have had chemotherapy treatment
- have nausea, vomiting, or diarrhea
- are pregnant or plan to become pregnant. Evomela can harm your unborn baby.

Females who can become pregnant:

- You should not become pregnant during treatment with Evomela.
- You should use effective birth control (contraception) during treatment and for 6 months after your last dose of Evomela.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with Evomela.

Males with female partners who can become pregnant:

- You should use effective birth control (contraception) during treatment and for 3 months after your last dose of Evomela.
- are breastfeeding or plan to breastfeed. It is not known if Evomela passes into your breast milk. You should not breastfeed during treatment and for 1 week after your last dose of Evomela.

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 Evomela?

- Evomela is given to you into your vein through an intravenous (IV) line over 30 minutes.
- Your healthcare provider will do blood tests before and during your treatment with Evomela.
- Your healthcare provider will prescribe medicines to help prevent nausea.

What are the possible side effects of Evomela?

Evomela may cause serious side effects, including:

- **Low blood cell counts** are common with Evomela and can be serious. Your healthcare provider will do blood tests as needed to check your blood counts during your treatment with Evomela.
 - **Low platelet counts:** Tell your healthcare provider right away if you have unusual bleeding or bruising under your skin.
 - **Low red blood cell counts:** Tell your healthcare provider if you are feeling weak, tired, or you get tired easily, you look pale, or you feel short of breath.
 - **Low white blood cell counts:** A low white blood cell count can cause you to get infections, which may be serious. Tell your healthcare provider right away if you have symptoms of infection, such as fever, chills, cough, pain, or burning during urination.

- **Redness and sores of the lining of the mouth, lips, throat, stomach, and genitals (mucositis). Mucositis is common during treatment with Evomela, and can sometimes be severe. Mucositis may cause discomfort or pain.**

Your healthcare provider will tell you about ways to maintain nutrition and help control the discomfort from mucositis, and may prescribe medicines if needed.

- **Nausea, vomiting, and diarrhea** are common with Evomela and can sometimes be severe. Tell your healthcare provider if you get nausea, vomiting, or diarrhea. Your healthcare provider may prescribe medicines to help

prevent or treat these side effects.

- **Liver problems.** Your healthcare provider will check you for liver problems during treatment with Evomela. Tell your healthcare provider right away if you get any of the following signs or symptoms:
 - yellowing of your skin or the whites of your eyes
 - severe nausea or vomiting
 - pain on the right side of your stomach-area (abdomen)
 - dark urine (tea colored)
- **Serious allergic reactions.** Tell your healthcare provider right away if you get any of the following signs or symptoms:
 - skin reactions, including welts, rash, itching, and redness
 - shortness of breath or trouble breathing
 - fast heartbeat
 - feel lightheaded or dizzy
 - chest tightness
 - blurry vision
 - wheezing
 - swelling of your face, tongue, or throatYour healthcare provider may need to discontinue treatment with Evomela if you have a serious allergic reaction.
- **Secondary cancers.** New cancers have happened in people who have been treated with Evomela.
- **Infertility.** Evomela may cause fertility problems in males and females. Talk to your healthcare provider if this is a concern for you. In females, your menstrual periods may stop due to treatment with Evomela.

The most common side effects of Evomela include: tiredness and low potassium level.

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

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

General information about the safe and effective use of Evomela.

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 Evomela that is written for health professionals.

What are the ingredients in Evomela?

Active ingredient: melphalan hydrochloride

Inactive ingredient: Betadex Sulfobutyl Ether Sodium

Manufactured for:
Acrotech Biopharma LLC
279 Princeton Hightstown Rd.
East Windsor, NJ 08520

For more information, go to www.evomela.com or call 1-888-292-9617.

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

Revised: August 2021