

PATIENT INFORMATION
POTELIGEO[®] (poe-te-lig'-ee-oh)
(mogamulizumab-kpkc)
injection, for intravenous use

What is the most important information I should know about POTELIGEO?

POTELIGEO may cause serious side effects that can be severe, life-threatening or lead to death.

Call or see your healthcare provider right away if you develop any symptoms of the following problems or if these symptoms get worse:

- **Skin problems.** Signs and symptoms of skin reactions may include:
 - skin pain
 - itching
 - skin blistering or peeling
 - rash
 - painful sores or ulcers in your mouth, nose, throat, or genital area
- **Infusion reactions.** Signs and symptoms of infusion reactions may include:
 - chills or shaking
 - redness on your face (flushing)
 - itching or rash
 - shortness of breath, coughing, or wheezing
 - dizziness
 - feeling like passing out
 - tiredness
 - fever
- **Infections.** Signs and symptoms of infection may include:
 - fever, sweats, or chills
 - nausea
 - flu-like symptoms
 - sore throat or difficulty swallowing
 - shortness of breath
 - diarrhea or stomach pain
 - cough
- **Autoimmune problems.** Some people receiving POTELIGEO develop autoimmune problems (a condition where the immune cells in your body attack other cells or organs in the body). Some people who already have an autoimmune disease may get worse during treatment with POTELIGEO.
- **Complications of stem cell transplantation that uses donor stem cells (allogeneic) after treatment with POTELIGEO.** These complications can be severe and can lead to death. Your healthcare provider will monitor you for signs of complications if you have an allogeneic stem cell transplant.

Getting medical treatment right away may help keep these problems from becoming more serious.

Your healthcare provider will check you for these problems during treatment with POTELIGEO. Your healthcare provider may need to delay or completely stop treatment with POTELIGEO if you have severe side effects.

What is POTELIGEO?

POTELIGEO is a prescription medicine used to treat mycosis fungoides (MF) or Sézary syndrome (SS) in adults when you have tried at least one prior medicine (taken by mouth or injection) and it did not work or the disease has come back.

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

Before receiving POTELIGEO treatment, tell your healthcare provider about all your medical conditions, including if you:

- have had a severe skin reaction after receiving POTELIGEO.
- have had an infusion-related reaction during or after receiving POTELIGEO.
- have or have had liver problems including hepatitis B (HBV) infection.
- have a history of autoimmune problems
- have undergone or plan to have a stem cell transplant, using stem cells from a donor.
- have lung or breathing problems
- are pregnant or plan to become pregnant. It is not known if POTELIGEO will harm your unborn baby.
 - If you are able to become pregnant, your healthcare provider will do a pregnancy test before you start treatment with POTELIGEO.
 - **Females** who are able to become pregnant should use an effective method of birth control during treatment with POTELIGEO and for at least 3 months after the last dose of POTELIGEO. Talk to your healthcare provider about birth control methods that you can use during this time. Tell your healthcare provider right away if you become pregnant during treatment with POTELIGEO.
- are breastfeeding or plan to breastfeed. It is not known if POTELIGEO passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with POTELIGEO.

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 POTELIGEO?

- Your healthcare provider will give you POTELIGEO into your vein through an intravenous (IV) line over at least 60 minutes.
- POTELIGEO is usually given on days 1, 8, 15, and 22 of the first 28-day cycle, then on days 1 and 15 of each 28-day cycle thereafter.
- Your healthcare provider will decide how many treatments you need based on how well you respond and tolerate the treatment.
- If you miss any appointments call your healthcare provider as soon as possible.

What are the possible side effects of POTELIGEO?**POTELIGEO may cause serious side effects including:**

- See “What is the most important information I should know about POTELIGEO?”

The most common side effects of POTELIGEO include:

- rash
- tiredness
- diarrhea
- muscle and bone pain
- upper respiratory tract infection

These are not all the possible side effects of POTELIGEO.

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 POTELIGEO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your healthcare provider or pharmacist for information about POTELIGEO that is written for healthcare professionals.

What are the ingredients in POTELIGEO?

Active ingredient: mogamulizumab-kpkc

Inactive ingredients: citric acid monohydrate, glycine, polysorbate 80, and Water for Injection, USP.

Manufactured by: Kyowa Kirin, Inc., Bedminster, NJ 07921 U.S. License No. 2077

POTELIGEO is a registered trademark of Kyowa Kirin, Inc.

For more information, call 1-844-768-3544 or go to www.POTELIGEO.com.

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

Issued: 08/2018