

STAY ENGAGED AND SUPPORTED THROUGHOUT Your treatment with POTELIGEO® (mogamulizumab-kpkc)

To encourage a smooth journey going forward, it's important to ask questions, gather information, and partner with your healthcare team.

- **Prepare** for your infusions and plan your schedule
- **Learn** about POTELIGEO by reading this brochure and other materials available at poteligeo.com
- **Communicate** with your healthcare team throughout the course of your treatment
- **Reach out** to Kyowa Kirin Cares for support

We're here to help.

Kyowa Kirin Cares provides dedicated, ongoing support for patients and their caregivers. From help with navigating financial options to providing personalized support throughout your journey with POTELIGEO, Kyowa Kirin Cares is here every step of the way.

Call 833-KK-CARES (833-552-2737) Monday through Friday, 8 AM to 8 PM (ET), to speak with a Kyowa Kirin Cares oncology nurse, or visit kyowakirincares.com/journey



WHAT TO KNOW AND EXPECT AS YOU GET STARTED ON Your treatment journey with POTELIGEO® (mogamulizumab-kpkc)

What is POTELIGEO?

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



Please see pages 6 and 7 for full Important Safety Information and accompanying Patient Information inside pocket.



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PM-US-POT-0166 December 2019



IMPORTANT SAFETY INFORMATION

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

POTEIGEO may cause serious side effects that can be severe or life-threatening including skin problems, infusion reactions, infections, autoimmune problems, and complications from stem cell transplant.

Please see pages 6 and 7 for additional Important Safety Information and accompanying Patient Information inside pocket.



BEFORE YOU GET STARTED, IT IS IMPORTANT TO KNOW

Your treatment schedule

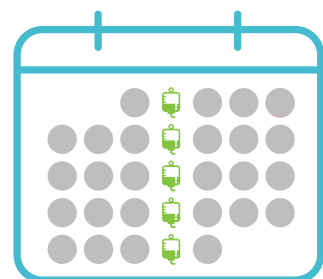
You may already know that POTELIGEO® is different from other treatments you have tried to manage MF or SS because, unlike an oral pill or cream applied to the skin, it is a systemic treatment administered by intravenous (IV) infusion.

As you get started, keep in mind that

- A trained healthcare provider will administer POTELIGEO at an infusion center or physician's office
- The infusion lasts for at least 1 hour
- Your healthcare provider will determine the appropriate schedule for your needs
- It is important to follow your POTELIGEO infusion schedule as directed
- If you miss an infusion, you should let your healthcare provider know right away

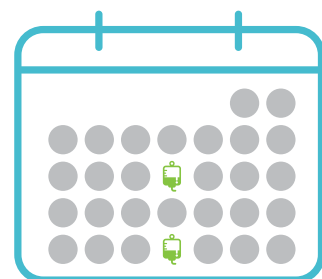
A sample infusion schedule is below. Note that the starting schedule and ongoing schedule are different.

Infusion schedule example



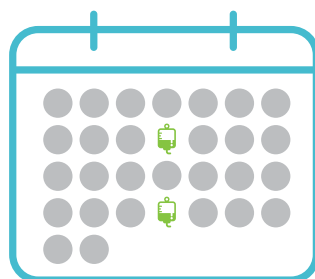
STARTING SCHEDULE

You will receive **1** infusion of POTELIGEO every week for the first **5** weeks.



ONGOING SCHEDULE

After the first **5** weeks, you will receive **1** infusion of POTELIGEO every other week.



Your infusion schedule may vary by up to 2 days.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

COMMIT TO YOUR INFUSION SCHEDULE

You may need to make adjustments to your everyday routine in order to stick to the infusion schedule. Here are some tips to help you stay on track:



Post a calendar on the fridge and/or add reminders on your phone



Ask for encouragement from those close to you, especially during the first month



Ask a family member or friend to accompany you to your infusion appointment



When going for your infusion, take items that bring you calm and comfort

IMPORTANT SAFETY INFORMATION (cont'd)

- **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 may develop autoimmune problems, and some people who already have an autoimmune disease may get worse during treatment with POTELIGEO.
- **Complications of stem cell transplant:** Patients who receive a stem cell transplant using donor stem cells (allogeneic) after treatment with POTELIGEO may experience complications that can be severe and lead to death. Your healthcare provider will monitor you for signs of complications if you have an allogeneic stem cell transplant.

What are the most common side effects of POTELIGEO?

The most common side effects of POTELIGEO include rash, tiredness, diarrhea, muscle and bone pain, and upper respiratory tract infection.

Before starting POTELIGEO treatment, tell your doctor about all your medical conditions, including whether you:

- have had a severe skin reaction after receiving POTELIGEO
- have had an infusion reaction during or after receiving POTELIGEO
- have or have had liver problems including hepatitis B (HBV) infection
- have a history of autoimmune problems

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WHAT YOU MAY EXPECT WITH

POTELIGEO® (mogamulizumab-kpkc) treatment

People living with MF or SS will experience unique journeys, and each person's treatment goals may vary. It is important to discuss your treatment goals with your healthcare provider.

1

How can I tell if POTELIGEO is working for me? POTELIGEO may help control MF and SS on the skin and inside the body. Therefore, some potential improvements may be visible to you and others may not. Your healthcare provider can do tests to assess your response to treatment.

2

How was POTELIGEO evaluated in clinical studies? POTELIGEO was studied in a large clinical trial for people with MF or SS, the most common subtypes of cutaneous T-cell lymphoma (CTCL). The clinical trial looked at the effectiveness and safety of POTELIGEO in the skin, blood, lymph nodes, and internal organs, and compared them with another CTCL treatment called vorinostat.

3

What were the main results of the clinical trial? Each person's experience with POTELIGEO may be different, but it may be helpful to know how other people with MF or SS responded:

- **Control over CTCL progression:** People taking POTELIGEO experienced control over their disease for more than twice as long as those taking vorinostat (median^a of 7.6 months vs 3.1 months, respectively)
- **Response to treatment:** More people taking POTELIGEO responded to treatment (improved by a certain amount) in 1 or more areas of the body (skin, blood, lymph nodes, and internal organs) compared with those taking vorinostat (28% vs 5%, respectively)
- **Time to response:** In the people who responded, the median time to response was 3.3 months for people taking POTELIGEO, compared with 5.1 months for those taking vorinostat
- **Duration of response:** In those who responded, people taking POTELIGEO experienced a longer-lasting response compared with vorinostat (median of 13.9 months vs 9.0 months, respectively)

4

Will I see improvements on my skin? In the clinical trial, 42% of people taking POTELIGEO experienced response to treatment on their skin vs 16% of people taking vorinostat.

IMPORTANT SAFETY INFORMATION (cont'd)

Before starting POTELIGEO treatment, tell your doctor about all your medical conditions, including whether you:

- have lung or breathing problems

For more detailed information about how POTELIGEO works and how it was assessed in a clinical trial, please refer to poteligeo.com/facts

BE AWARE OF POTENTIAL INFUSION-RELATED SIDE EFFECTS

As with any IV infusion, there is potential for infusion-related side effects. This risk may be greater when you first begin treatment but should lessen as you continue and your body has time to adjust.

To reduce the occurrence of these side effects, your healthcare provider may prescribe medications to take on the day you start treatment with POTELIGEO.

Let your healthcare provider know right away if you experience any symptoms such as chills or shaking, nausea, fever, rapid heartbeat, headache, or vomiting.

AN IMPORTANT NOTE ABOUT SKIN REACTIONS

Rash (or drug eruption) is a common side effect of POTELIGEO. The rash may occur at any time, and the appearance and location of the rash may vary. It may even appear as if your skin symptoms are getting worse when they are not. In the POTELIGEO clinical trial, most cases (82%) were mild or moderate in severity. Tell your healthcare provider if you think you may be experiencing a rash. If so, he or she may prescribe a topical medicine such as a corticosteroid and may consider temporarily or permanently stopping POTELIGEO treatment.

^aIn this brochure, median refers to the middle length of time that a treatment effect was observed. This means that half of people experienced the treatment effect for a shorter time than the median time and half of people experienced the treatment effect for a longer time than the median time.

IMPORTANT SAFETY INFORMATION (cont'd)

Before starting POTELIGEO treatment, tell your doctor about all your medical conditions, including whether you:

- have undergone or plan to have a stem cell transplant, using cells from a donor
- are pregnant or plan to become pregnant
 - It is not known if POTELIGEO will harm your unborn baby
- are breastfeeding or plan to breastfeed
 - Talk to your healthcare provider about the best way to feed your baby during treatment with POTELIGEO

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

You are encouraged to report suspected adverse reactions to Kyowa Kirin, Inc. at 1-844-768-3544 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see pages 6 and 7 for additional Important Safety Information and accompanying Patient Information inside pocket.

 **POTELIGEO**[®]
(mogamulizumab-kpkc) Injection
Targeted for Control

Important Safety Information

What is POTELIGEO® (mogamulizumab-kpkc)?

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

IMPORTANT SAFETY INFORMATION

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

POTELIGEO may cause serious side effects that can be severe or life-threatening including skin problems, infusion reactions, infections, autoimmune problems, and complications from stem cell transplant.

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 may develop autoimmune problems, and some people who already have an autoimmune disease may get worse during treatment with POTELIGEO.
- **Complications of stem cell transplant:** Patients who receive a stem cell transplant using donor stem cells (allogeneic) after treatment with POTELIGEO may experience complications that can be severe and lead to death. Your healthcare provider will monitor you for signs of complications if you have an allogeneic stem cell transplant.

What are the most common side effects of POTELIGEO?

The most common side effects of POTELIGEO include rash, tiredness, diarrhea, muscle and bone pain, and upper respiratory tract infection.

Before starting POTELIGEO treatment, tell your doctor about all your medical conditions, including whether you:

- have had a severe skin reaction after receiving POTELIGEO
- have had an infusion 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 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
- are breastfeeding or plan to breastfeed
 - Talk to your healthcare provider about the best way to feed your baby during treatment with POTELIGEO

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

You are encouraged to report suspected adverse reactions to Kyowa Kirin, Inc. at 1-844-768-3544 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying Patient Information inside pocket.

For more information, including questions to ask your doctor, visit www.poteligeo.com

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