



# Staying on Track

A guide to your treatment with  
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, life-threatening or lead to death. Call or see your healthcare provider right away if you develop any symptoms including skin problems, infusion reactions, infections, autoimmune problems, and complications from stem cell transplant.

Please see page 7 for additional Important Safety Information and accompanying Patient Information.

# Get the most out of your treatment by paying attention to what's going on

You and your healthcare provider have decided to get you started with POTELIGEO® (mogamulizumab-kpkc) as a treatment for mycosis fungoides (MF) or Sézary syndrome (SS). Make sure you get the most out of it by knowing what to expect. You can do your part to manage symptoms and side effects by tracking them.


## Understanding the clinical trial results of POTELIGEO


Remember that when used as directed, POTELIGEO may help control your MF or SS on the skin *and* inside the body.

In a clinical trial that compared the effectiveness and safety of POTELIGEO to vorinostat (another MF or SS treatment) in the blood, lymph nodes, and internal organs, patients taking POTELIGEO had the following results:

### Effectiveness

 **3x**  
greater rate and duration of  
**response in blood**

 **28%**  
of patients saw **reduction** in  
the amount of **disease**

 **42%**  
of patients experienced  
**response to treatment on  
their skin**

 **2%**  
of patients saw **no evidence of  
disease** after treatment  
with **POTELIGEO**

### Time to response

Control over MF or SS  
lasted an average of

 **7+**  
MONTHS

Response to POTELIGEO  
lasted an average of

 **13+**  
MONTHS

### 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.

Please see page 7 for additional Important Safety Information and accompanying Patient Information.

# What to expect during treatment

As you get your POTELIGEO® (mogamulizumab-kpkc) infusions, keep in mind that results take time—it may take around 3 months to see results. You should track any side effects and symptoms between appointments. Knowing what side effects to look for and keeping an eye out for a rash that may occur later into treatment are important parts of managing your treatment experience with POTELIGEO.

## Side effects to look out for

This risk for side effects may be greater when you first begin treatment, but they should lessen as you continue once your body has time to adjust.

### THE MOST COMMON SIDE EFFECTS OF POTELIGEO

- Rash
- Tiredness
- Diarrhea
- Muscle and bone pain
- Upper respiratory tract infection
- Infusion site reaction
- Skin reaction

To reduce the occurrence of these side effects, your healthcare provider may prescribe medications to take on the same 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.

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## An important note about skin reactions

Some of the most noticeable symptoms of MF or SS on the skin include rash, bumps or lesions, tumors, ulcers and infections. However, a few months into treatment, you may notice a skin reaction or redness on your skin, which your healthcare provider may refer to as a “drug eruption.”

- This is a common side effect of POTELIGEO.
- In the POTELIGEO clinical trial, most cases of drug eruption were mild or moderate (82%) in severity.
- Reach out to your healthcare provider to understand what kind of reaction you are having and what you should do next.

## 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:**

- **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.

**Please see page 7 for additional Important Safety Information and accompanying Patient Information.**

# My Symptom Tracker

Your healthcare provider will conduct tests to help assess your overall responsiveness to treatment, but it's also important for you to let them know how you're feeling if something new arises or if you're noticing any new patterns in how you feel between appointments.

Track what you're noticing or feeling in this chart and share it with your healthcare provider. Print out as many of these charts as you need and keep them together for reference. You can also use the **My Body Scanner** exercise after the tracker to pinpoint the exact location on your body where you're noticing something during your treatment with POTELIGEO® (mogamulizumab-kpkc).

What I noticed	When I noticed it	What I did
<i>Make note of anything you feel might be related to your treatment or to your MF or SS</i>	<i>Record the day</i>	<i>How did I manage it? How long did it persist?</i>
Rash (see My Body Scanner for exact location).	11/12	Lotions and creams for now – will keep monitoring. I took a picture so I can show my healthcare provider.



## SPEAK UP

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

## 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:**

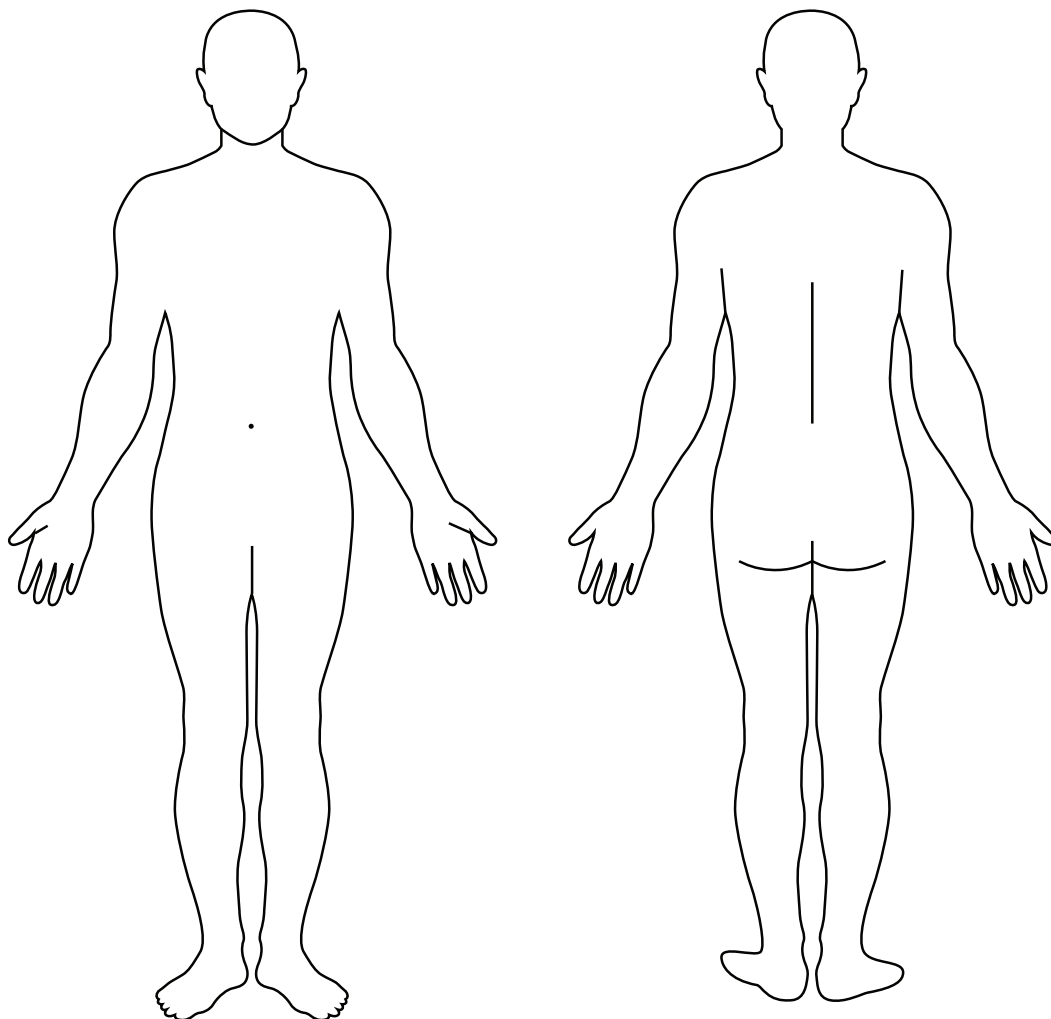
- **Complications of stem cell transplant:** Patients who receive a stem cell transplant using donor stem cells (allogeneic) after treatment with POTELIGEO may experience complications that can be severe and lead to death. Your healthcare provider will monitor you for signs of complications if you have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

**Please see page 7 for additional Important Safety Information and accompanying Patient Information.**

## My Body Scanner

As you receive your POTELIGEO® (mogamulizumab-kpkc) infusions, it may also help to use the body images below to identify where on your body you're noticing something. For example, if you notice a rash on your left forearm, you can circle or shade in the exact place on the appropriate image below. Then you can track if there are any changes using the tracker on the previous page.

You can also share these images with your healthcare provider to help them understand what you're experiencing.



### TAKE A PICTURE

Snap a photo daily so you can share accurate details, including these body scanner images, with your healthcare provider at your next appointment.

### IMPORTANT SAFETY INFORMATION (cont'd)

#### 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.


**Please see page 7 for additional Important Safety Information and accompanying Patient Information.**


# Keep communicating

Keeping your healthcare team in the loop can help them best support you. Plus, it can help you stay on track with treatment and manage your mycosis fungoides (MF) or Sézary syndrome (SS).

## Make it a partnership during appointments *and* in between them

 **Share** what you're tracking and how you're feeling both physically and emotionally.

 **Write down** questions using the prompts below so you'll have them top of mind.

 **Ask** to have instructions written down or take your own notes during conversations.

## Questions for my healthcare provider

Think about 1 or 2 things you specifically want to discuss with your healthcare team. Write them down below so you can bring them up at your next appointment. This could be anything you want to learn more about, such as symptom management, treatment schedules, emotional wellness, financial support, or MF or SS disease education.


1 \_\_\_\_\_


2 \_\_\_\_\_


## Learn a simple way to reduce stress

As you're tracking what's going on with your body, you may be feeling worried or stressed. This is normal. But too much stress can have a negative impact on your health. Reducing stress can be as simple as taking a moment to stop what you are doing and clear your thoughts. Try it out below.

Close your eyes and put every thought, worry, or feeling you are having away. Then, think of a place, person, image, or sound that makes you relax. For example, it could be

 Standing outside on a breezy day, feeling the cool wind on your face and body.

 Reading a favorite book or magazine outside, smelling the fresh air.

 Listening to your favorite song, following along with the lyrics or rhythm.

Whatever it is, envision your own example or scenario of what makes you feel calm, sound of mind, joyful, and most like yourself. Keep focusing on this vision and the smells, feelings, tastes, and images it brings to mind. Do this for a few minutes to help reduce stress and clear your thoughts.

Anytime you're having negative thoughts or feeling stressed, go back to your vision, activity, or song.

## IMPORTANT SAFETY INFORMATION (cont'd)

**Before starting POTELIGEO® (mogamulizumab-kpkc) 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

**Please see page 7 for additional Important Safety Information and accompanying Patient Information.**

# 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](http://www.fda.gov/medwatch).**

**Please see accompanying Patient Information.**

To speak with a Kyowa Kirin Cares nurse, call 833-KK-CARES (833-522-2737) Monday through Friday, 8 AM to 8 PM (ET).

For more information, visit [www.kyowakirincares.com](http://www.kyowakirincares.com).



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**PATIENT INFORMATION**  
**POTELIGEO**<sup>®</sup> (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](http://www.POTELIGEO.com).

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

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