

Living with mycosis fungoides (MF) or Sézary syndrome (SS)
and ready for a different treatment?

Regain control. Maintain control.

In the clinical trial, people taking POTELIGEO experienced control over their disease for more than twice as long as those taking the comparator treatment vorinostat (median of 7.6 months vs 3.1 months, respectively) and, of people in the trial who responded to treatment, response lasted 54% longer in people taking POTELIGEO compared with those taking the comparator treatment (median of 13.9 months vs 9.0 months, respectively).

What is POTELIGEO®?

POTELIGEO is a prescription medicine used to treat MF or 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.

Please see pages 12 and 13 for additional Important Safety Information and accompanying Patient Information.



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

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Glossary terms

You will notice we have included some glossary terms throughout this brochure; look for the underlined words and corresponding definitions on pages 14 and 15. If you have any questions about the content in this brochure, talk to your healthcare provider.

GETTING STARTED WITH



Each person's treatment goals may vary, but you may have decided it's time for something different because:



Your current treatment(s) may not be working as well as it did before, has stopped working altogether, and/or has caused bothersome side effects



You have noticed new or worsening skin symptoms, and/or test results have shown that your disease has spread beyond the skin to other areas of your body



Your disease is affecting your life, and you are ready to try a different treatment

If this sounds like you, don't lose hope. POTELIGEO may offer you something different.

LET'S GET STARTED

IMPORTANT SAFETY INFORMATION

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 pages 12 and 13 for additional Important Safety Information and accompanying Patient Information.

POTELIGEO® IS A

targeted systemic therapy

POTELIGEO is a targeted therapy for adults with MF or SS who have tried at least 1 prior systemic treatment (taken by mouth or injection) that did not work or in whom the disease has come back.

POTELIGEO is a



Systemic treatment



Treatment given by IV infusion



Treatment that specifically targets cancer cells

POTELIGEO is *not* a



Topical treatment



Treatment taken by mouth



Chemotherapy

Because POTELIGEO is an intravenous (IV) infusion, it will be given at an infusion center by a trained healthcare provider. There is more information about the infusion experience on page 10.



Underline indicates a glossary term. See pages 14 and 15 for definitions.

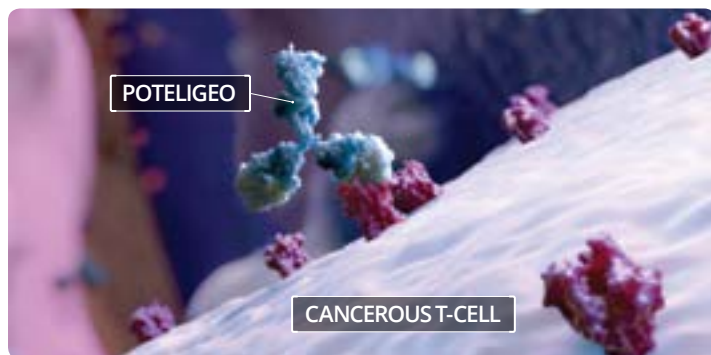
IMPORTANT SAFETY INFORMATION (cont'd)

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.

POTELIGEO IS DIFFERENT FROM OTHER treatments you have tried

POTELIGEO is a **monoclonal antibody** that binds to certain cancerous T-cells, triggering your body's immune cells to specifically target them. No other treatment for MF and SS works exactly the same way; let's take a closer look.



POTELIGEO works by specifically latching on to cancerous T-cells, while aiming to leave your healthy cells alone.



Once POTELIGEO latches on, it attracts certain types of immune cells in your body to come attack the cancer cells.

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:

- **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.

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THE EFFECTIVENESS OF POTELIGEO® was studied in a large clinical trial

POTELIGEO was studied in the largest clinical trial to date for a systemic treatment for people with the most common cutaneous T-cell lymphoma (CTCL) subtypes MF and SS. The [phase 3 clinical trial](#) evaluated the safety and effectiveness of treatment with POTELIGEO compared with the safety and effectiveness of a [comparator treatment](#) called vorinostat, a drug used in the United States to treat CTCL.

The trial looked at the 4 areas of the body where MF or SS could be found:



Skin



Blood



Lymph nodes



Internal organs

Effectiveness was evaluated in the following ways:

- **How well treatment prevented MF and SS from spreading further.** Your healthcare provider may also refer to this as “[progression-free survival](#).”
- **How well treatment reduced MF and SS in areas of the body where disease was found when entering the trial.** Your healthcare provider may also refer to this as “response to treatment” or “overall response rate.”
- **How long people responded to treatment.** Your healthcare provider may also refer to this as “duration of response.”

IMPORTANT SAFETY INFORMATION (cont'd)

What are the most common side effects of POTELIGEO?

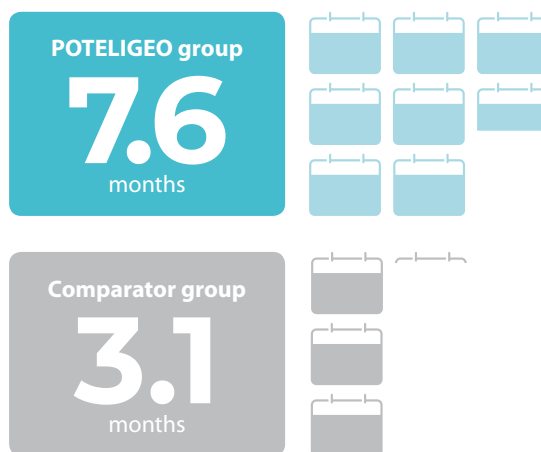
- The most common side effects of POTELIGEO include rash, tiredness, diarrhea, muscle and bone pain, and upper respiratory tract infection.


POTELIGEO MAY HELP

control MF and SS on the skin and inside the body

In the clinical trial, people taking POTELIGEO experienced control over their disease for more than twice as long as those taking the comparator treatment.

Median number of months that MF or SS was controlled before showing any sign of spreading further



 Underline indicates a glossary term. See pages 14 and 15 for definitions.

IMPORTANT SAFETY INFORMATION (cont'd)

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

Please see pages 12 and 13 for additional Important Safety Information and accompanying Patient Information.

 **POTELIGEO**[®]
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MORE PEOPLE TAKING POTELIGEO®

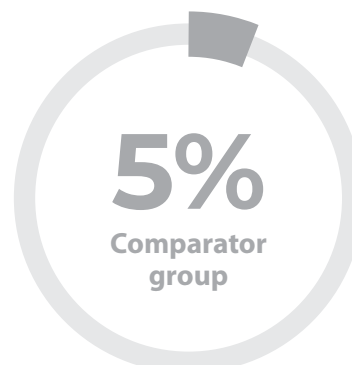
responded to treatment vs those taking the comparator

In the clinical trial, response to treatment was divided into 2 categories: partial response and complete response. Partial response was defined as a reduction in the amount of cancer in the body; complete response was defined as no evidence of disease in the body.

Percentage of people who experienced partial response in 1 or more areas of the body (skin, blood, lymph nodes, and internal organs) or complete response



2% of people who used POTELIGEO experienced complete response vs 0 taking the comparator treatment.



IMPORTANT SAFETY INFORMATION (cont'd)

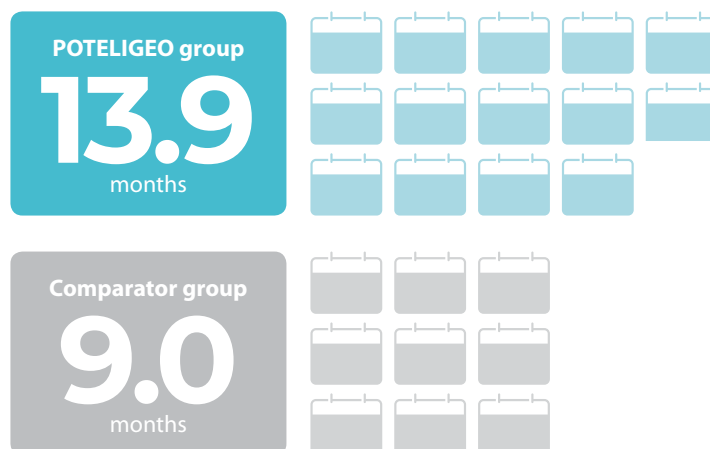
Before starting POTELIGEO treatment, tell your doctor about all your medical conditions, including whether you:

- 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

IN THOSE WHO RESPONDED, PEOPLE TAKING POTELIGEO experienced longer-lasting response vs those taking the comparator

Response to treatment lasted 54% longer in people taking POTELIGEO vs those taking the comparator treatment.

Median number of months of partial or complete response (once response was first detected)



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
- 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.

Please see pages 12 and 13 for additional Important Safety Information and accompanying Patient Information.

 **POTELIGEO**[®]
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POTELIGEO® IS

given as an IV infusion

POTELIGEO is an intravenous (IV) infusion and will be given at an infusion center by a trained healthcare provider. Each infusion will last at least 1 hour.

Make the most of your POTELIGEO infusion time.

Be sure to plan ahead about how you'd like to spend your time while you receive POTELIGEO treatments. We've included some suggestions below:



Watch a
TV show



Call a family member
or friend to catch up



Read a book



Play a game



Pick up a
new hobby
(eg, knitting)

Remember, a trained healthcare provider will be available to assist you and answer any questions you may have during your treatments.

IMPORTANT SAFETY INFORMATION (cont'd)

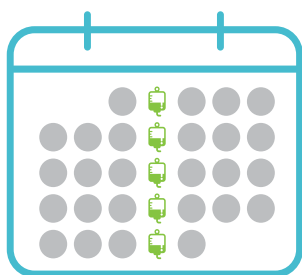
What is the most important information I should know about POTELIGEO?

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.

THE POTELIGEO infusion schedule

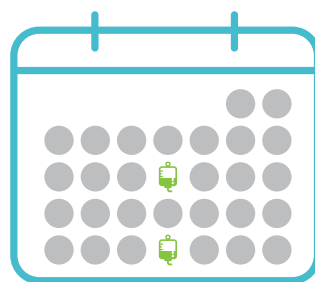
It's important to know that there is a starting infusion schedule and an ongoing infusion schedule. You will receive POTELIGEO once per week for the first 5 weeks and then once every 2 weeks as shown below.

Infusion schedule example



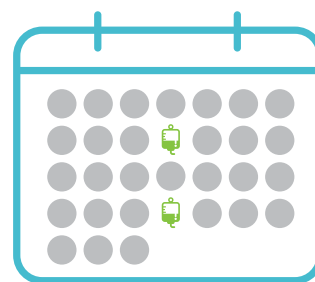
STARTING SCHEDULE

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 can vary by up to 2 days, but be sure not to receive POTELIGEO infusions less than 5 days apart.

Look out for 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.

Please see pages 12 and 13 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.

Please see accompanying Patient Information.

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



Glossary terms

Chemotherapy: A type of treatment that attacks fast-growing cells. Cancer cells are fast growing—but some healthy cells are also fast growing. Chemotherapy cannot tell the difference between the two, so it attacks both cancer cells and fast-growing healthy cells.

Comparator treatment: A currently available FDA-approved treatment used in clinical trials to compare with an investigational treatment that is not yet approved for use. In the phase 3 clinical trial, efficacy and safety of POTELIGEO® was studied vs the comparator treatment, vorinostat, a drug that is approved for use in people with CTCL.

Median: In general, median describes the middle number in a sequence of numbers. Throughout 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.

Monoclonal antibody: A type of drug designed to latch on to 1 substance—in this case, cancer cells. Once it latches on, the monoclonal antibody recruits naturally occurring cells in your body’s immune system to come attack the cancer cells.

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.

Phase 3 clinical trial: A type of trial that evaluates the safety and effectiveness of an investigational treatment against the current standard treatment. In the POTELIGEO phase 3 clinical trial, POTELIGEO was the investigational treatment and vorinostat (the comparator treatment) was the current standard treatment.

Progression-free survival: The amount of time from when a person starts receiving a treatment to when their disease gets worse, or until the person dies from any cause. In a clinical study, progression-free survival (also referred to as PFS) is one way to evaluate how well a new treatment works.

Systemic treatment: A treatment taken by mouth, injection, or IV infusion that works inside the body.

Targeted therapy: A type of systemic treatment that specifically attacks cancer cells while aiming to leave healthy cells alone. Targeted therapies may not affect you in quite the same way that chemotherapies might—and side effects can vary depending on what the therapy targets.

Topical treatment: A treatment applied to the skin. Topical treatments are typically used as a primary treatment for CTCL and can also be used in combination with systemic treatments.

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.

Please see pages 12 and 13 for additional Important Safety Information and accompanying Patient Information.



KYOWA KIRIN cares

ACCESS • ASSISTANCE • UNDERSTANDING

Kyowa Kirin Cares is a program that offers comprehensive support for people who have been prescribed POTELIGEO®. From help with navigating financial options to providing ongoing and personalized support throughout your journey with POTELIGEO, Kyowa Kirin Cares is here every step of the way.

To learn more about how Kyowa Kirin Cares can help you, visit www.kyowakirincares.com/patient

Most commercially insured patients:



KYOWA KIRIN

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 **POTELIGEO**[®]
(mogamulizumab-kpkc) Injection
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poteligeo.com

kyowakirincares.com

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Fax: 844-267-5848

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 1-800-844-3544 or go to www.POTELIGEO.com.

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

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