

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 lifethreatening including skin problems, infusion reactions, infections, autoimmune problems, and complications from stem cell transplant.



What is CTCL?



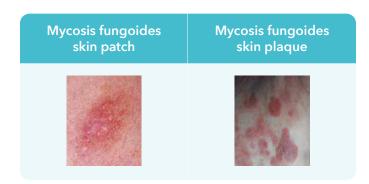
Cutaneous T-cell lymphoma (CTCL) is a rare cancer of white blood cells called T cells

Healthy T cells are a key part of the immune system that help the body fight infections and diseases. In CTCL, T cells grow too rapidly and become cancerous, affecting the skin and potentially the blood, lymph nodes, and internal organs.

CTCL can appear in different ways

In more common forms of CTCL, cancerous T cells are usually first found in the skin.

 Cancerous T cells in the skin can appear as flat areas called patches or slightly raised areas called plaques. They may cause sunburn-like redness or rashes, and sometimes skin tumors



The 2 most common types of CTCL are mycosis fungoides, also called MF, and Sézary syndrome, also called SS

Important Safety Information (continued)

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.

What is mycosis fungoides (MF)?

MF is the most common type of CTCL

MF can affect the skin with symptoms such as rash, itchy skin, skin lesions (changes in skin color or texture), or tumors. Research shows that most people with MF only experience skin symptoms and can have a normal life span.

- In about 1 out of 3 people with MF, cancerous T cells may spread within the skin and to other parts of the body, including the lymph nodes and other organs
- For some people with MF, cancerous T cells may be in or spread to the blood
 - You may hear your doctor call this "blood involvement"

Blood involvement in MF

- If you have MF with blood involvement, the number of cancerous T cells in your blood may increase if your disease worsens or if your current treatment is not right for you
- The more cancerous T cells you have in your blood, the more serious your MF may be

Important Safety Information (continued)

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

- 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 is Sézary syndrome (SS)?

SS is less common and has different symptoms

SS is a type of CTCL that can cause symptoms including itchy, red skin that may look like a sunburn over most of the body. In all people with SS, cancerous T cells are found in the blood.

- In some people with SS, cancerous T cells may spread to other parts of the body such as the lymph nodes or other organs
- The number of cancerous T cells in your blood may increase if your disease worsens or if your current treatment is not right for you

Important Safety Information (continued)

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

Blood testing in MF and SS



Blood testing can measure cancerous T cells



One way to track blood involvement is a flow cytometry test, which can help identify and measure the amount of cancerous T cells in your blood, if any are present.

- Your doctor can also do this test to see if the number of cancerous T cells has increased or decreased by comparing your current results to past results
- Stay ahead of your MF or SS by talking to your doctor about receiving a blood test if you experience any new or worsening symptoms

If you have MF or SS with increasing blood involvement, your doctor may consider a different treatment option

Important Safety Information (continued)

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

- 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



What is POTELIGEO?



POTELIGEO is a targeted immunotherapy that helps your immune system attack cancerous T cells

POTELIGEO is not a chemotherapy. POTELIGEO is a medicine your doctor can prescribe for MF or SS if you have tried at least 1 prior medicine (taken by mouth or injection) that did not work or if your MF or SS has come back after treatment.

POTELIGEO is:

- **V**
- Given through an infusion into the vein/bloodstream, known as an intravenous (IV) infusion
- V

Specifically designed to target cancerous T cells

POTELIGEO is not:

- **X** Chemotherapy
- X Applied to the skin
- X Taken by mouth

POTELIGEO latches onto cancer cells and attracts certain types of cells called immune cells that help your body fight infection or other harmful substances, including cancer.

- POTELIGEO fights your cancer in ways you don't even see. It works on your skin and the cancer cells inside your body in other areas that may be affected, such as the blood, lymph nodes, and other organs
- Slowing the spread of cancerous T cells in the body may help improve MF or SS

POTELIGEO may help control MF and SS on the skin and in the blood

Important Safety Information (continued)

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

Is POTELIGEO right for you?

POTELIGEO is a chemo-free treatment that may help with either MF or SS

Ask your doctor about POTELIGEO if your current treatments are:

- Not working
- Not working as well as they used to
- Causing unwanted side effects

POTELIGEO may be appropriate for you if:

- You are already on treatment, but see new skin symptoms or your skin symptoms are getting worse
- Your MF or SS has spread to other parts of your body
- Your MF or SS is causing worsening symptoms and you're ready to try a different treatment

POTELIGEO isn't right for everyone-always talk to your doctor about your treatment options

Important Safety Information (continued)

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.



POTELIGEO was studied in a large clinical trial



POTELIGEO was studied in people who tried at least 1 prior medicine (taken by mouth or injection) that did not work or whose MF or SS had come back or spread.

• The clinical trial studied the safety of POTELIGEO and how it worked compared against another treatment called vorinostat

How POTELIGEO worked was evaluated in 4 different ways

Your doctor may say	How POTELIGEO was evaluated
Progression-free survival (PFS)	How well treatment prevented MF or SS from spreading further
Overall response rate (ORR)	How well treatment reduced MF or SS in areas of the body where disease was found when entering the trial
Time to response (TTR)	How long it took people with MF or SS to respond to treatment
Duration of response (DoR)	How long people with MF or SS responded to treatment

Important Safety Information (continued)

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.

POTELIGEO can help control MF and SS on the skin and inside the body

POTELIGEO helped slow the spread of MF and SS

POTELIGEO helped keep MF and SS under control for approximately 2 times longer than when compared with vorinostat

Median time that MF or SS was controlled before showing signs of spreading further

7.6 VS 3.1 MONTHS

Important Safety Information (continued)

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

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- 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.



More people responded to treatment with POTELIGEO

To be considered a responder, people had to experience:

50% skin improvement

Skin symptoms cleared up by 50% or more

50% improvement in other areas

At least a 50% improvement in their blood, lymph nodes, or other organs No worsening symptoms

Symptoms in the skin, blood, lymph nodes, or other organs did not get worse

More than 5 times as many people were classified as responders to treatment with POTELIGEO than with vorinostat





Over 2 times as many people taking POTELIGEO

saw their skin symptoms improve (42% responded with POTELIGEO vs 16% with vorinostat)

Nearly 4 times as many people taking POTELIGEO

saw a lower cancerous T-cell count in their blood (67% responded with POTELIGEO vs 18% with vorinostat)

Important Safety Information (continued)

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

- **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.

Overall time to response and duration of response were better with POTELIGEO

Overall time to response with POTELIGEO was nearly 2 months faster

People responded to treatment with POTELIGEO nearly 2 months faster than treatment with vorinostat (median 3.3 months with POTELIGEO vs 5.1 months with vorinostat).

POTELIGEO worked longer than vorinostat

Of people in the trial who responded to treatment, response lasted longer for people taking POTELIGEO compared with those taking vorinostat (median of 13.9 months with POTELIGEO vs 9.0 months with vorinostat).

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



With POTELIGEO, you may not see your skin get better right away—your doctor may see changes in your blood test results before your skin symptoms improve

Important Safety Information (continued)

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 is given as an infusion



IV therapy involves giving medication through a vein with a needle. This is done by a trained healthcare professional at an infusion center. The needle delivers medicine directly into the bloodstream.

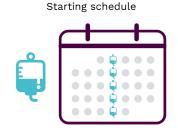
- Each infusion of POTELIGEO will take at least 1 hour
- A trained healthcare professional will administer POTELIGEO at an infusion center

- It's important to follow your POTELIGEO infusion schedule as directed
- If you miss an infusion, you should let your healthcare professional know right away

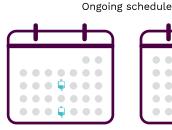
Infusion scheduling with POTELIGEO

You will be given 1 infusion of POTELIGEO every week for the first 5 weeks. After the first 5 weeks, you will be given 1 infusion of POTELIGEO every 2 weeks. Your infusion schedule may vary by up to 2 days.

Your schedule may be different. Always discuss your infusion schedule with your doctor.



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After the first 5 weeks, you will be given 1 infusion of POTELIGEO every 2 weeks.

Important Safety Information (continued)

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

You may experience side effects related to your infusions

With any IV therapy, infusion-related reactions are possible

You may be more likely to experience infusion-related reactions during your first few infusions, but the chances of experiencing them should lessen as your body gets used to treatment.

- Let your healthcare professional know right away if you experience any symptoms such as chills or shaking, nausea, fever, rapid heartbeat, headache, or vomiting during or after your infusions
- To reduce the occurrence of these side effects, your doctor may prescribe medications for you to take before infusions

Skin-related reactions are also possible

- Rash is a possible side effect of POTELIGEO. Your doctor may call this a drug eruption. If you experience a reaction, it
 doesn't necessarily mean POTELIGEO isn't working
- Rash may occur at any time, and the appearance and location of the rash may vary
- In the POTELIGEO clinical trial, most cases of rash (82%) were mild or moderate

Tell your doctor if you think you may be experiencing a rash. You may be prescribed a topical medicine such as a corticosteroid, and your doctor will determine if it's necessary to pause or stop treatment with POTELIGEO.



What to look for. A skin reaction may occur on your body and look like redness or a rash.



When it could appear. Side effects may occur at any time after you receive POTELIGEO.



When to call your doctor. If you notice any kind of reaction, contact your doctor to understand the symptoms and what you should do next.

Important Safety Information (continued)

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

have or have had liver problems including hepatitis B (HBV) infection



Preparing for your infusions



After you and your doctor choose POTELIGEO, there are different ways you can get ready for your infusion. On infusion day, a healthcare professional will welcome you, take your vital signs, and administer treatment with POTELIGEO.

Considerations for infusion day



Plan your time accordingly

Infusions of POTELIGEO take at least 1 hour, not including travel, prep, and monitoring.



Set infusion reminders

Post a calendar on your refrigerator and/or add reminders on your phone.



Commit to your infusion schedule

You may need to adjust your everyday routine to stick to the infusion schedule.



Ask for support

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



Review your medications

Discuss with your doctor any medications you take or should take to help with side effects.



Bring comfort with you

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

Important Safety Information (continued)

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

- 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

Getting comfortable on infusion day

Try activities to keep you busy Watch a TV show Read a book Play a game Call a family member or friend new hobby

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

Wear warm, comfortable clothing. Pick your clothes out the night before. Wearing loose-fitting, warm clothes like a sweatshirt or sweatpants will make it easier for you to stay warm and comfortable during your infusion and can make the experience a little better.

Consider bringing a family member or friend. Depending on your infusion center, you may be able to bring a family member or a friend for company and support. Someone should drive you to and from at least your first few infusions.

Find your support system. It's important to find a group of people you can depend on for support. They can be your family, friends, or even the CTCL community. If you're unsure about your support system or would like more information about the CTCL community, talk to your care team.

Keep track of your journey. Use page 17 as a place to keep important notes from your doctor visits and infusion days.

Important Safety Information (continued)

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

- 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

POTELIGEO® (mogamulizumab-kpk

Important Safety Information for POTELIGEO

What is POTELIGEO® (mogamulizumab-kpkc)?

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- 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.

Use this page to keep track of information from your doctor visits and infusion days.	Notes:
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Get support for your journey with POTELIGEO from Kyowa Kirin Cares

Kyowa Kirin Cares is a patient support program with dedicated specialists and case managers who can connect patients and caregivers to the support they need. From help with navigating financial options to personalized support throughout your journey with POTELIGEO, we are here every step of the way.



Information about POTELIGEO



Infusion process support



Tips for staying on track with treatment



Insurance and financial support information



Educational tools and resources

For more information and to enroll, visit www.POTELIGEO.com



Call 833-KK-CARES (833-552-2737)

Monday through Friday, 8 AM to 8 PM ET, to speak with a Kyowa Kirin Cares case manager



Scan with your phone's camera to learn more about Kyowa Kirin Cares

Information provided by a dedicated specialist is for informational purposes only and does not constitute medical advice. It is not intended to replace a discussion between you and your healthcare professional. All decisions regarding your care must be made by your healthcare professional.

Please see page 16 for Important Safety Information, and accompanying Patient Information on page 19.





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:

o skin pain o rash

o itching o painful sores or ulcers in your mouth, nose,

skin blistering or peeling throat, or genital area

• Infusion reactions. Signs and symptoms of infusion reactions may include:

o chills or shaking

dizziness

redness on your face (flushing)

o feeling like passing out

itching or rash

tirednessfever

shortness of breath, coughing, or wheezing

Infections. Signs and symptoms of infection may include:

fever, sweats, or chills

shortness of breath

o nausea

o diarrhea or stomach pain

flu-like symptoms

cough

sore throat or difficulty swallowing

- 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.
 - o 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 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

muscle and bone pain

tiredness

upper respiratory tract infection

diarrhea

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., Princeton, NJ 08540 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.

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