

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.