

Package leaflet: Information for the patient

POTELIGEO 4 mg/mL concentrate for solution for infusion mogamulizumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What POTELIGEO is and what it is used for
2. What you need to know before you use POTELIGEO
3. How POTELIGEO is given
4. Possible side effects
5. How to store POTELIGEO
6. Contents of the pack and other information

1. What POTELIGEO is and what it is used for

POTELIGEO contains the active substance mogamulizumab, which belongs to a group of medicines called monoclonal antibodies. Mogamulizumab targets cancer cells which are then destroyed by the immune system (the body's defence).

This medicine is used to treat adults with mycosis fungoides and Sézary syndrome, which are types of cancers called cutaneous T-cell lymphomas. The medicine is for use in patients who have received at least one medicine given by mouth or by injection.

2. What you need to know before you use POTELIGEO

Do not use POTELIGEO

- if you are allergic to mogamulizumab or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or nurse before using POTELIGEO if you:

- ever had a severe skin reaction with this medicine.
- ever had an infusion reaction with this medicine (possible symptoms of an infusion reaction are listed in section 4).
- have human immunodeficiency virus (HIV), herpes, cytomegalovirus (CMV), or hepatitis B or C infection, or other on-going infections.
- have had or plan to have a stem cell transplant, either using your own cells or a donor's.
- have had tumour lysis syndrome (a complication involving the destruction of cancer cells) after a previous treatment.
- have heart problems.

Tell the person giving you the infusion or get medical help straight away if you experience a reaction during or after any POTELIGEO infusion.

Tell your doctor immediately if you experience any of the serious side effects listed in Section 4 after starting POTELIGEO treatment.

Other medicines and POTELIGEO

Tell your doctor if you are taking, have recently taken, or might take any other medicines.

Children and adolescents

This medicine should not be used in children and adolescents below 18 years of age.

Pregnancy and breast-feeding

The effects of POTELIGEO in pregnancy and breast-feeding are not known. Due to the mechanism of action of the medicine, it may harm your baby if it is administered when you are pregnant or breast-feeding.

If you can get pregnant, you will need to use effective contraception during and for at least six months after receiving this treatment. If you are breast-feeding, you should discuss with your doctor whether you can breast-feed during or after treatment with POTELIGEO.

You must tell your doctor or nurse if you are pregnant, breast-feeding, think you may be pregnant, or are planning to have a baby.

Driving and using machines

POTELIGEO is unlikely to affect your ability to drive and use machines. However, the medicine can cause tiredness in some people, so take particular care when driving and using machines until you are certain that this medicine does not affect you.

POTELIGEO contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. How POTELIGEO is given

The amount of POTELIGEO you will receive is calculated by your doctor based on your body weight. The recommended dose is 1mg POTELIGEO for each kg of body weight.

POTELIGEO will be given to you through a vein (intravenous infusion) over at least 60 minutes. To start with, the infusions will be given once a week for the first 5 doses, then once every 2 weeks. Treatment should be continued unless you get serious side effects or the cutaneous T-cell lymphoma starts to get worse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Tell your doctor or nurse or get medical help immediately if you have any of the following signs and symptoms after starting POTELIGEO:

- **Very common side effects (may affect more than 1 in 10 people):** chills, nausea or vomiting, headache, wheezing, itching, flushing, rash, dizziness or feeling faint, difficulty breathing and fever, which may be signs of an infusion reaction. If this happens, the infusion may need to be stopped and you may require additional treatment. When the symptoms go away, POTELIGEO can normally continue to be given, but more slowly. Your doctor may stop POTELIGEO treatment if your reaction is severe.
- signs of infection, which may include a fever, sweats or chills, flu-like symptoms, sore throat or difficulty swallowing, cough, shortness of breath, stomach pain, nausea or vomiting, diarrhoea and feeling very unwell.

- skin rash (which may become severe), or sore mouth. In some people receiving POTELIGEO for other types of cancers, skin pain/burning sensation, itching, skin blisters//peeling, ulcers in the mouth or on the lips or genitals occurred, which are possible signs of a severe skin reaction, such as Stevens-Johnson syndrome or toxic epidermal necrolysis (which affected up to 1 in 100 people).

Uncommon side effects (may affect up to 1 in 100 people):

- fever, chills, nausea, vomiting, confusion, shortness of breath, seizures, irregular heartbeat, dark or cloudy urine, unusual tiredness and/or muscle or joint pain. The destruction of cancer cells and the body's reaction to it can very occasionally lead to a problem called tumour lysis syndrome.
- chest pain, shortness of breath, fast or slow heartbeat, sweating, dizziness, nausea or vomiting, weakness, feeling faint and feeling unwell. Although unlikely to be caused by this medicine, these may be signs of a heart disorder.

Not known (frequency cannot be estimated from the available data):

- if you go on to have a stem cell transplant, it is possible that you could then develop complications (graft versus host disease) that are difficult to manage. Symptoms may include skin rashes or blistering, nausea or diarrhoea that doesn't go away, stomach pain or vomiting, joint pain or stiffness, dry or irritated eyes or blurred vision, mouth sores, irritation or pain, a cough that does not go away or difficulty breathing, sensitive genitals, jaundice (turning yellow), dark urine, and any swelling.

Other side effects

Talk to your doctor if you get any other side effects. These can include:

Very common side effects (may affect more than 1 in 10 people):

- Lack of energy (fatigue)
- Constipation
- Swollen legs or ankles
- Headache

Common side effects (may affect up to 1 in 10 people):

- Anaemia (reduced red blood cells)
- Reduced blood platelets (thrombocytopenia)
- Reduced white blood cells (neutropenia and leucopenia) or reduced lymphocytes
- Blood tests showing raised liver enzyme levels
- Underactive thyroid

Uncommon side effects (may affect up to 1 in 100 people)

- Inflammation of the liver (hepatitis)

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store POTELIGEO

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the vial after "EXP". The expiry date refers to the last day of that month.

Unopened vial: Store in a refrigerator (2°C - 8°C). Do not freeze.

Store in the original carton in order to protect from light

Reconstituted/diluted solution: Use immediately or store in a refrigerator (2°C - 8°C) and use within 24 hours.

Do not use this medicine if you notice signs of deterioration, such as particulate matter or discolouration.

Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

6. Contents of the pack and other information

What POTELIGEO contains

- Each vial contains 20 mg of mogamulizumab in 5 mL of concentrate, corresponding to 4 mg/mL.
- The other excipients are citric acid monohydrate, glycine, polysorbate 80, sodium hydroxide, hydrochloric acid, and water for injections. See section 2 “POTELIGEO contains sodium”.

What POTELIGEO looks like and contents of the pack

POTELIGEO is a clear, colourless solution. The pack contains a glass vial containing 5 mL concentrate for solution for infusion.

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