

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using POTELIGEO?

POTELIGEO contains the active ingredient mogamulizumab. POTELIGEO is used to treat adults with mycosis fungoides or Sézary syndrome, which are types of cancers called cutaneous T-cell lymphomas.

For more information, see [Section 1. Why am I using POTELIGEO?](#) in the full CMI.

2. What should I know before I use POTELIGEO?

Do not use it if you have ever had an allergic reaction to POTELIGEO or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines or are pregnant or plan to become pregnant or are breast-feeding.

For more information, see [Section 2. What should I know before I use POTELIGEO?](#) in the full CMI.

3. What if I am taking other medicines?

No studies have been performed to find out which medicines interfere with POTELIGEO and affect how it works.

For more information, see [Section 3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use POTELIGEO?

- The amount of POTELIGEO you will receive is calculated by your doctor based on your 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.

More information can be found in [Section 4. How do I use POTELIGEO?](#) in the full CMI.

5. What should I know while using POTELIGEO?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using POTELIGEO.• Tell the person giving you the infusion or get medical help straight away if you experience a reaction during or after any POTELIGEO infusion.
Things you should not do	<ul style="list-style-type: none">• Do not stop attending your appointments for your POTELIGEO infusion.
Driving or using machines	<ul style="list-style-type: none">• POTELIGEO can affect your ability to drive and use machines. This medicine may cause tiredness after it has been given. Be careful before you drive or use any machines or tools until you know how POTELIGEO affects you.
Looking after your medicine	<ul style="list-style-type: none">• POTELIGEO will be stored in refrigerated conditions (2°C to 8°C) in the hospital or pharmacy.

For more information, see [Section 5. What should I know while using POTELIGEO?](#) in the full CMI.

6. Are there any side effects?

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

- chills, nausea, vomiting, headache, wheezing, itching, flushing, rash, dizziness or feeling faint, difficulty breathing and fever, which may be signs of an **infusion reaction**.

For more information, including what to do if you have any side effects, see [Section 6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

POTELIGEO[®]

Active ingredient(s): *Mogamulizumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using POTELIGEO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using POTELIGEO.**

Where to find information in this leaflet:

- [1. Why am I using POTELIGEO?](#)
- [2. What should I know before I use POTELIGEO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use POTELIGEO?](#)
- [5. What should I know while using POTELIGEO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using POTELIGEO?

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

This medicine is used to treat adults with mycosis fungoides or Sézary syndrome, which are types of cancers called cutaneous T-cell lymphomas. POTELIGEO will be prescribed only after you have tried another medicine given by mouth or by injection.

2. What should I know before I use POTELIGEO?

Warnings

Do not use POTELIGEO if:

- you are allergic to mogamulizumab, or any of the other ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- develop a skin reaction with this medicine. Fatal and life threatening skin reactions have occurred in some patients who have taken POTELIGEO.
- develop signs of infection including skin infections. This includes signs and symptoms such as fever, sweats, chills, flu-like symptoms, sore throat or skin sores or blisters that leak pus or fluid.

- develop an infusion reaction with this medicine (possible symptoms of an infusion reaction are listed in [Section 6](#)).
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under [Section 6. Are there any side effects?](#)

Pregnancy and breast-feeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breast-feeding or intend to breast-feed.

The effects of POTELIGEO in pregnancy and breast-feeding are not known. Due to the effect of the medicine in your body, 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 three 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.

Men

You will need to use effective contraception during and for at least three months after receiving this treatment.

Children and adolescents

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect POTELIGEO.

4. How do I use POTELIGEO?

How much to use

The amount of POTELIGEO you will receive is calculated by your doctor based on your body weight.

How POTELIGEO is given

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. You and your doctor will decide how long to stay on POTELIGEO. You may get serious side effects or the medicine may stop working.

It is recommended to take a medicine to treat fever and an anti-histamine (used for allergic reactions) before the first POTELIGEO infusion. If an infusion reaction (See [Section 6 "Serious side effects"](#)) occurs, these medicines are needed for subsequent POTELIGEO infusions.

If you are given too much (overdose)

As POTELIGEO is given to you under the supervision of your doctor it is unlikely that you will be given too much. However, if you experience any side effects after being given POTELIGEO, tell your doctor immediately.

5. What should I know while using POTELIGEO?

Things you should do

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 6](#) after starting POTELIGEO treatment.

Remind any doctor, dentist or pharmacist you visit that you are using POTELIGEO.

Things you should not do

Do not stop attending your appointments for your POTELIGEO infusion. You should advise your doctor immediately if you cannot attend the appointment to receive your infusion. It is important that you speak with your doctor to discuss re-scheduling your appointment as soon as possible.

Driving and using machines

Be careful before you drive or use any machines or tools until you know how POTELIGEO affects you.

POTELIGEO can affect your ability to drive and use machines. This medicine may cause tiredness after it has been given.

Looking after your medicine

- POTELIGEO must be stored in a refrigerator (2°C to 8°C) in the hospital or pharmacy.
- Do not freeze.
- Do not shake.
- Keep the vial in the outer carton in order to protect from light.

POTELIGEO contains sodium

This medicine contains less than 23 mg sodium per vial. Talk to your doctor or pharmacist about your sodium intake.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Blood related: <ul style="list-style-type: none">• Anaemia (reduced red blood cells)• Reduced blood platelets (thrombocytopenia)• Reduced white blood cells (neutropenia and leucopenia) or reduced lymphocytes Endocrine related: <ul style="list-style-type: none">• Underactive thyroid Digestive organ related: <ul style="list-style-type: none">• Constipation General disorders: <ul style="list-style-type: none">• Lack of energy (fatigue)• Swollen legs or ankles Liver related: <ul style="list-style-type: none">• Inflammation of the liver (hepatitis)• Raised liver enzyme levels Head related: <ul style="list-style-type: none">• Headache	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Possible signs of an infusion reaction: <ul style="list-style-type: none"> • Chills • Nausea • Vomiting • Headache • Wheezing • Itching • Flushing • Rash • Dizziness or feeling faint • Difficulty breathing • Fever 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
Possible signs of infection: <ul style="list-style-type: none"> • Fever • Sweats or chills • Flu-like symptoms • Sore throat or difficulty swallowing • Cough • Shortness of breath • Stomach pain • Nausea or vomiting • Diarrhoea • Feeling very unwell • Skin sores or blisters that leak pus or fluid that may be painful Signs that you may be developing a severe skin reaction, such as Stevens-Johnson syndrome or toxic epidermal necrolysis: <ul style="list-style-type: none"> • Skin pain • Itching • Skin blisters • Skin rash • Sore mouth Possible signs of a heart disorder: <ul style="list-style-type: none"> • Chest pain • Shortness of breath • Fast or slow heartbeat • Sweating • Dizziness • Nausea or vomiting • Weakness • Feeling faint • Feeling unwell 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
Possible signs of tumour lysis syndrome: <p>The destruction of cancer cells and the body's reaction to it can very occasionally lead to a problem called tumour lysis syndrome.</p> <ul style="list-style-type: none"> • Fever • Chills • Nausea • Vomiting • Confusion • Shortness of breath • Seizures • Irregular heartbeat • Dark or cloudy urine • Unusual tiredness and/or muscle or joint pain 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
Possible signs of graft versus host disease: <p>If you have had or go on to have a stem cell transplant due to your conditions, complications (graft versus host disease) that are difficult to manage may develop after the transplant.</p> <ul style="list-style-type: none"> • 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 • Any swelling 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting of side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What POTELIGEO contains

Active ingredient (main ingredient)	Mogamulizumab
Other ingredients (inactive ingredients)	The other excipients are citric acid monohydrate, glycine, polysorbate 80, sodium hydroxide, hydrochloric acid, and water for injections. See Section 5 “POTELIGEO contains sodium” .

Do not use this medicine if you are allergic to any of these ingredients.

What POTELIGEO looks like and contents of the pack

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

Who distributes POTELIGEO

Kyowa Kirin Australia Pty Ltd
Level 7
68 York Street
Sydney, NSW 2000

enquiry.kkau@kyowakirin.com

Medical enquiries: 02 9320 2200

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