



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Poteligeo (*mogamulizumab*)

An overview of Poteligeo and why it is authorised in the EU

What is Poteligeo and what is it used for?

Poteligeo is a cancer medicine used to treat mycosis fungoides and Sezary syndrome – two cancers of blood cells that affect mainly the skin. It is used in patients who have received previous treatment by mouth or injection.

Both mycosis fungoides and Sezary syndrome belong to a group of rare cancers (cutaneous T-cell lymphomas), and Poteligeo was designated an 'orphan medicine' (a medicine used in rare diseases) on 14 October 2016. Further information on the orphan designation can be found here:

ema.europa.eu/Find_medicine/Human_medicines/Rare_disease_designation

Poteligeo contains the active substance mogamulizumab.

How is Poteligeo used?

Poteligeo can only be obtained with a prescription and treatment should be supervised by a doctor who has experience in the treatment of cancer and in a place where equipment for resuscitation is available in case of rare and severe allergic reaction to the medicine.

The medicine is given as an infusion (drip) into a vein lasting at least 1 hour. The recommended dose depends on the patient's body weight and is given once a week for the first 4 weeks and then every 2 weeks. Patients should be monitored during and after the infusion for certain side effects related to the infusion. To reduce this risk, patients may be given other medicines such as an antipyretic (medicine that reduces fever) and an antihistamine (for treating allergic reactions) before or during treatment with Poteligeo.

The doctor may interrupt or stop treatment, or reduce the dose, if the patient develops certain serious side effects.

For more information about using Poteligeo, see the package leaflet or contact your doctor or pharmacist.



How does Poteligeo work?

The active substance in Poteligeo, mogamulizumab, is a monoclonal antibody (a type of protein) that has been designed to attach to a receptor (target) called CCR4. CCR4 is found on the surface of white blood cells, including the cancerous cells in mycosis fungoides or Sezary syndrome. By attaching to CCR4, mogamulizumab stimulates the body's immune system to attack the cancer cells, helping to control the disease.

What benefits of Poteligeo have been shown in studies?

Poteligeo was shown to be more effective than a comparator medicine, vorinostat, in a study of 372 adults with either mycosis fungoides or Sezary syndrome. In this study, patients receiving Poteligeo lived for around 8 months without their disease getting worse compared with 3 months for patients on vorinostat.

In all patients the cancer did not respond to a previous treatment or had come back.

What are the risks associated with Poteligeo?

The most common side effects with Poteligeo (seen in more than 1 patient in 10) are infusion-related reactions and rash. The most commonly reported serious reactions are pneumonia (infection of the lungs), fever, infusion-related reactions and cellulitis (inflammation of the deep skin tissue).

For the full list of side effects and restrictions with Poteligeo, see the package leaflet.

Why is Poteligeo authorised in the EU?

Poteligeo is effective at prolonging the time patients with mycosis fungoides or Sezary syndrome live without their disease getting worse. Effects are clinically relevant considering that patients have limited treatment options. The side effects seen with Poteligeo are considered manageable and most of them are mild or moderate. The European Medicines Agency therefore decided that Poteligeo's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Poteligeo?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Poteligeo have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Poteligeo are continuously monitored. Side effects reported with Poteligeo are carefully evaluated and any necessary action taken to protect patients.

Other information about Poteligeo

Poteligeo received a marketing authorisation valid throughout the EU on 22 November 2018.

Further information on Poteligeo can be found on the Agency's website: ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports.

This overview was last updated in 11-2018.