



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/754186/2017
EMA/H/C/ 004536

EPAR summary for the public

Prevymis

letermovir

This is a summary of the European public assessment report (EPAR) for Prevymis. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Prevymis.

For practical information about using Prevymis, patients should read the package leaflet or contact their doctor or pharmacist.

What is Prevymis and what is it used for?

Prevymis is an antiviral medicine used to prevent illness caused by cytomegalovirus (CMV) in adults having an allogeneic haematopoietic stem cell transplant to replace their bone marrow. Allogeneic haematopoietic stem cell transplantation involves using stem cells from a donor to replace the recipient's bone marrow cells to form new bone marrow that produces healthy blood cells.

Many people have CMV in their body but it is usually inactive and it does not cause harm. However, CMV can become active in patients whose immune system is weakened such as those having stem cell transplants.

Because the number of patients with CMV disease is low, the disease is considered 'rare', and Prevymis was designated an 'orphan medicine' (a medicine used in rare diseases) on 15 April 2011.

Prevymis contains the active substance letermovir.

How is Prevymis used?

Prevymis can only be obtained with a prescription, and treatment should be started by a doctor experienced in managing patients who have had an allogeneic haematopoietic stem cell transplant. Doctors should consider official guidance on the use of antiviral medicines when using Prevymis.



Prevymis is available as tablets to be taken by mouth and as a concentrate that is made up into a solution for infusion (drip) into a vein and given over about an hour. The usual recommended dose by mouth or as an infusion is 480 mg once daily. If ciclosporin (a medicine that prevents rejection of the transplant) is used at the same time, the Prevymis dose is reduced to 240 mg once daily. Treatment with Prevymis is started on the day of the transplant or on any day up to 28 days afterwards and it is continued for 100 days after the transplantation; longer treatment may be considered in some patients. For further information, see the package leaflet.

How does Prevymis work?

For CMV to multiply, its genetic material (DNA) needs to be copied and packaged into protein shells to produce more viruses that can then infect other cells. Letermovir, the active substance in Prevymis, blocks a virus enzyme called 'terminase'. Terminase is involved in packaging the DNA in the protein shells of the virus. By blocking the enzyme, the medicine prevents viruses from developing properly, so that CMV cannot multiply and infect other cells. This is expected to prevent CMV disease in transplant recipients who already have CMV in their body.

What benefits of Prevymis have been shown in studies?

A main study involving 570 adults found Prevymis was more effective than placebo (a dummy treatment) in preventing CMV infection after allogeneic haematopoietic stem cell transplantation. Of the patients receiving Prevymis, about 38% (122 out of 325) had signs of CMV becoming active 24 weeks after the stem cell transplant compared with 61% of the patients (103 out of 170) receiving placebo.

All patients in this study were CMV seropositive, meaning they had come into contact with the virus before and were likely to be carrying it in an inactive form.

What are the risks associated with Prevymis?

The most common side effects with Prevymis (which may affect up to 1 in 10 people) are nausea (feeling sick), diarrhoea and vomiting. For the full list of side effects reported with Prevymis, see the package leaflet.

Prevymis must not be used together with the medicine pimozide, or ergot medicines such as ergotamine and dihydroergotamine. The combination of Prevymis and ciclosporin must not be used with dabigatran, atorvastatin, pitavastatin, rosuvastatin and simvastatin. For the full list of restrictions, see the package leaflet.

Why is Prevymis approved?

Prevymis is effective in preventing CMV from becoming active and causing disease in adult recipients of a stem cell transplantation to replace the bone marrow. It has few side effects unlike other medicines used for the treatment of CMV disease which can damage bone marrow and affect blood cells. The European Medicines Agency therefore decided that Prevymis's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

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

Other information about Prevymis

The European Commission granted a marketing authorisation valid throughout the European Union for Prevymis on 8 January 2018.

The full EPAR for Prevymis can be found on the Agency's website: ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports. For more information about treatment with Prevymis, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Prevymis can be found on the Agency's website: ema.europa.eu/Find/medicine/Human_medicines/Rare_disease_designation.

This summary was last updated in 01-2018.