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# Prevymis (*letermovir*)

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

## What is Prevymis and what is it used for?

Prevymis is an antiviral medicine used to prevent illness caused by cytomegalovirus (CMV) in adults and children who have received an allogeneic haematopoietic stem cell transplant (HSCT) or a kidney transplant. For HSCT, Prevymis is used in children who weigh at least 5 kg; for kidney transplants, it is used in children who weigh at least 40 kg.

Allogeneic HSCT 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. The medicine is used when the HSCT recipient is seropositive (has previously had a CMV infection). In patients receiving a kidney transplant, the medicine is used when the donor is seropositive.

Following CMV infection many people still have CMV in their body, but it is usually inactive and does not cause harm. However, CMV can become active when the immune system (the body's natural defences) is weakened, such as when having a transplant.

CMV disease is rare, and Prevymis was designated an 'orphan medicine' (a medicine used in rare diseases) on 15 April 2011. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/eu311849.

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 HSCT or kidney transplant. Doctors should consider official guidance on the use of antiviral medicines when using Prevymis.

For patients weighing at least 15 kg, Prevymis is available as tablets to be taken by mouth. For patients weighing at least 5 kg, it is available as granules to be mixed with food or given through a feeding tube or as a concentrate to be made up into a solution for infusion (drip) into a vein.

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Treatment generally lasts up to 100 days after transplantation for patients receiving an HSCT, and 200 days for patients receiving a kidney transplant. In some HSCT patients, treatment up to 200 days may also be considered.

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

## 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. The active substance in Prevymis, letermovir, blocks an enzyme (protein) made by the virus 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 can prevent CMV disease in HSCT recipients who are CMV seropositive, and in people receiving a kidney from a CMV-seropositive donor.

## What benefits of Prevymis have been shown in studies?

A main study involving 570 CMV seropositive adults found Prevymis was more effective than placebo (a dummy treatment) in preventing CMV infection after allogeneic HSCT. Of the patients receiving Prevymis, about 38% (122 out of 325) had signs of CMV becoming active 24 weeks (around 100 days) after the stem cell transplant compared with 61% of the patients (103 out of 170) receiving placebo. An additional study showed that this effect was maintained up to week 28 (around 200 days) after the transplant.

Another main study involving 589 adults showed that Prevymis was effective in preventing CMV disease in seronegative patients who received a kidney from a seropositive donor. One year after the transplant, about 10% (30 out of 289) of patients given Prevymis had signs of active CMV disease, compared with 12% (35 out of 297) of patients given the comparator medicine valganciclovir.

A third main study involved 63 children from birth up to less than 18 years who were at risk of CMV infection after allogeneic HSCT. The study results showed that in children weighing at least 5 kg, Prevymis behaves in the body in the same way as in adults. Supportive data from this study indicated that around 11% (6 out of 56) of the treated children had signs of CMV becoming active 24 weeks after the stem cell transplant. The study did not compare Prevymis with placebo or another medicine to treat CMV.

## What are the risks associated with Prevymis?

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

The most common side effects with Prevymis (which may affect up to 1 in 10 people) include nausea (feeling sick), diarrhoea and vomiting.

Prevymis must not be used together with certain medicines because doing so can affect the way either Prevymis or the other medicine works, reducing their effects or leading to side effects.

## Why is Prevymis authorised in the EU?

Prevymis is effective in preventing CMV from becoming active and causing disease in adults and children who receive an HSCT or in those who receive a kidney transplant. For stem cell

transplantation, Prevymis can be used in children weighing at least 5 kg. As there are no data on the use of Prevymis in children receiving a kidney transplant, its approved use in these children is based on data from studies in adults. Therefore, Prevymis can only be used in children receiving a kidney transplant who weigh at least 40 kg.

Prevymis 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 it can be authorised 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.

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

## Other information about Prevymis

Prevymis received a marketing authorisation valid throughout the EU on 8 January 2018.

Further information on Prevymis can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/prevymis.

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