Package leaflet: Information for the patient

PREVYMIS® 240 mg film-coated tablets
PREVYMIS® 480 mg film-coated tablets
letermovir

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking 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, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What PREVYMIS is and what it is used for

PREVYMIS is an antiviral prescription medicine that contains the active substance letermovir.

PREVYMIS is a medicine for adults who have recently had a bone marrow transplant. The medicine helps stop you from getting ill from CMV ('cytomegalovirus').

CMV is a virus that a lot of people have without knowing. Normally, CMV just stays in their body and it does not hurt them. However, if your immune system is weak after you get a bone marrow transplant, you may be at high risk of becoming ill from CMV.

2. What you need to know before you take PREVYMIS

Do not take PREVYMIS if:
- you are allergic to letermovir or any of the other ingredients of this medicine (listed in section 6).
- you take either of these medicines:
  - pimozide - used for Tourette's syndrome
  - ergot alkaloids (such as ergotamine and dihydroergotamine) - used for migraine headaches.
- you take the following herbal product:
  - St. John's wort (*Hypericum perforatum*)

Do not take PREVYMIS if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before taking PREVYMIS.

If you are taking PREVYMIS with ciclosporin, do not take the following medicines:
- dabigatran - used for blood clots

- atorvastatin, simvastatin, rosuvastatin, pitavastatin - for high cholesterol.

Warnings and precautions
If you are also taking a medicine for high cholesterol (see list of medicines in section "Other medicines and PREVYMIS" below) you must tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever. Your medicine or dose may then need to be changed. See the package leaflet for your other medicine for further information.

Additional blood tests may be needed to monitor the following medicinal products:
- Ciclosporin, tacrolimus, sirolimus
- Voriconazole

Children and adolescents
PREVYMIS is not for use in children and adolescents under 18 years old. This is because PREVYMIS has not been tested in this age group.

Other medicines and PREVYMIS
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is because PREVYMIS may affect the way other medicines work, and other medicines may affect how PREVYMIS works. Your doctor or pharmacist will tell you if it is safe to take PREVYMIS with other medicines.

There are some medicines you **must not take** with PREVYMIS (see list under "Do not take PREVYMIS if:").
There are some additional medicines you **must not take** with PREVYMIS and ciclosporin (see list under "If you are taking PREVYMIS with ciclosporin, do not take the following medicines:").

Also tell your doctor if you are taking any of the following medicines. This is because your doctor may have to change your medicines or change the dose of your medicines:
- alfentanil - for severe pain
- fentanyl - for severe pain
- quinidine - for abnormal heart rhythms
- ciclosporin, tacrolimus, sirolimus - used to prevent transplant rejection
- voriconazole - for fungal infections
- statins, such as atorvastatin, fluvastatin, rosuvastatin, simvastatin, pravastatin, pitavastatin - for high cholesterol
- glyburide, repaglinide - for high blood sugar
- carbamazepine, phenobarbital, phenytoin - for fits or seizures
- dabigatran, warfarin - used to thin the blood or for blood clots
- midazolam - used as a sedative
- amiodarone - used to correct irregular heartbeats
- oral contraceptive steroids - for birth control
- omeprazole, pantoprazole - for stomach ulcers and other stomach problems
- nafcillin - for bacterial infections
- rifabutin, rifampicin - for mycobacterial infections
- thioridazine - for psychiatric disorders
- bosentan - for high blood pressure in the vessels in the lungs
- efavirenz, etravirine, nevirapine, lopinavir, ritonavir - for HIV
- modafinil - for wakefulness

You can ask your doctor or pharmacist for a list of medicines that may interact with PREVYMIS.

Pregnancy
If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine. PREVYMIS is not recommended in pregnancy. This is because it

has not been studied in pregnancy and it is not known if PREVYMIS will harm your baby while you are pregnant.

Breast-feeding
If you are breast-feeding or are planning to breast-feed, tell your doctor before taking this medicine. Breast-feeding is not recommended while taking PREVYMIS. This is because it is not known if PREVYMIS gets in your breast milk and will be passed to your baby.

Driving and using machines
PREVYMIS may have minor influence on your ability to drive and use machines (see section 4 Possible side effects below). Some patients have reported fatigue (feeling very tired) or vertigo (feeling like you are spinning) during treatment with PREVYMIS. If you experience any of these effects, do not drive or use machines until the effect wears off.

PREVYMIS contains lactose
PREVYMIS contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. How to take PREVYMIS

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take
The recommended dose of PREVYMIS is one 480 mg tablet once a day. If you also take ciclosporin, your doctor will decrease the dose of PREVYMIS to one 240 mg tablet once a day.
- Take PREVYMIS at the same time every day.
- Take it with or without food.

How to take
- Swallow the tablet whole with some water. Do not break, crush, or chew the tablet.

If you take more PREVYMIS than you should
If you take more PREVYMIS than you should, call your doctor straight away.

If you forget to take PREVYMIS
It is very important that you do not miss or skip doses of PREVYMIS.
- If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Take your next dose at the usual time.
- Do not take two doses of PREVYMIS at the same time to make up for a missed dose.
- If you are not sure what to do, call your doctor or pharmacist.

Do not stop taking PREVYMIS
Do not stop taking PREVYMIS without talking to your doctor first. Do not run out of PREVYMIS. This will give the medicine the best chance to keep you from becoming ill from CMV after you get a bone marrow transplant.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

4. Possible side effects

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

Common: may affect up to 1 in 10 people
- diarrhoea
- feeling sick (nausea)
- being sick (vomiting)

Uncommon: may affect up to 1 in 100 people
- allergic reaction (hypersensitivity) – the signs may include wheezing, difficulty breathing, rashes or hives, itchiness, swelling
- loss of appetite
- changes in taste
- headache
- feeling like you are spinning (vertigo)
- stomach ache
- abnormalities in laboratory tests of liver function
- muscle spasms
- high blood creatinine - shown in blood tests
- feeling very tired (fatigue)
- swelling of hands or feet

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist, 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 at 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 PREVYMIS

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 blister card after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What PREVYMIS contains
The active substance is letermovir. Each film-coated tablet contains 240 mg letermovir or 480 mg letermovir.

The other ingredients are:
Tablet core
Microcrystalline cellulose (E460), croscarmellose sodium (E468), povidone (E1201), colloidal anhydrous silica (E551), magnesium stearate (E470b).
Film-coating
Lactose monohydrate, hypromellose (E464), titanium dioxide (E171), triacetin (E1518), iron oxide yellow (E172), iron oxide red (only for 480 mg tablets) (E172), carnauba wax (E903).

What PREVYMIS looks like and contents of the pack
PREVYMIS 240 mg film-coated tablets
PREVYMIS 240 mg film-coated tablet is a yellow oval tablet, debossed with "591" on one side and MSD logo on the other side. The tablet is 16.5 mm long and 8.5 mm wide.
The 240 mg tablets are packaged into a carton containing four (4) 7-count Polyamide/Aluminium/PVC – Aluminium blister cards for a total of 28 tablets.

PREVYMIS 480 mg film-coated tablets
PREVYMIS 480 mg film-coated tablet is a pink oval, bi-convex tablet, debossed with "595" on one side and MSD logo on the other side. The tablet is 21.2 mm long and 10.3 mm wide.
The 480 mg tablets are packaged into a carton containing four (4) 7-count Polyamide/Aluminium/PVC – Aluminium blister cards for a total of 28 tablets.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder in Great Britain: Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London, EC2M 6UR, UK.

Marketing Authorisation Holder in UK (Northern Ireland): Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands.

Manufacturer: Schering-Plough Labo NV, Industriepark 30 – Zone A, B-2220 Heist-op-den-Berg, Belgium.

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Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu.

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