

PREVYMIS[®] Film-Coated Tablet

Consumer Medication Information Leaflet
(RiMUP)

Letermovir (240mg and 480mg)

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Please read this information carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information may have changed. Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

What PREVYMIS is used for

PREVYMIS is a prescription medicine for adults who have recently had a stem cell (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 stem cell transplant, you may be at high risk of becoming ill from CMV.

How PREVYMIS works

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

Before you take PREVYMIS

When you must not use it

Do not take PREVYMIS if:

- you are allergic to letermovir or any of the other ingredients of this medicine (listed in section Product Description).

- You take either of these medicines:
 - Pimozide – used for Tourette's syndrome
 - Ergot alkaloids (such as ergotamine and dihydroergotamine) - used for migraine headaches

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 cyclosporine, do not take the following medicines:

- Dabigatran – used for blood clots
- Atorvastatin, simvastatin, rosuvastatin, pitavastatin, lovastatin – for high cholesterol

Before you start to use it

Warnings and precautions

If you are also taking a medicine for high cholesterol (see list of medicines in section "Taking other medicines" 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:

- Cyclosporine, tacrolimus, sirolimus
- Voriconazole

Report any muscle pain or tenderness while taking a statin.

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. Breastfeeding 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.

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.

Taking other medicines

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 "*When you must not use it.*"

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.
- cyclosporine, tacrolimus, sirolimus - used to prevent transplant rejection
- voriconazole - for fungal infections
- statins, such as atorvastatin, fluvastatin, rosuvastatin, simvastatin, pravastatin, pitavastatin, lovastatin – for high

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- 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, rifampin (for mycobacterial infections)
- thioridazine (for psychiatric disorders)
- bosentan (for high blood pressure in the vessels in the lungs)
- St. John's wort (*Hypericum perforatum*) (an herbal product)
- efavirenz, etravirine, nevirapine (for HIV)
- modafinil (for wakefulness)

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

How to take PREVYMIS

How much to take

You can receive PREVYMIS® two different ways: as tablets or through an IV (intravenously).

If you take the tablets:

The recommended dose of PREVYMIS is one 480 mg tablet once a day. If you also take cyclosporine, 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.

When to use it

Take PREVYMIS at the same time every day.

Take PREVYMIS with or without food.

Swallow the tablet whole with some water. Do not break, crush, or chew the tablet.

How long to use it

PREVYMIS should be taken as directed by your health care provider. Do not stop taking PREVYMIS without talking to your doctor first.

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

If you forget to use it

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.

If you use too much (overdose)

If you take more PREVYMIS than your prescribed dose, call your doctor right away.

While you are taking PREVYMIS

Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking PREVYMIS.

Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

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.

Do not give PREVYMIS to anyone else, even if they have the same symptoms or condition as you.

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

Things to be careful of

Driving and using machines

PREVYMIS may have minor influence on your ability to drive and use machines (see section 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.

This medicine contains less than 1 mmol sodium (23 mg) per 240 mg tablet, that is to say essentially 'sodium-free'.

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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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of PREVYMIS

Storage

Store below 30°C.
Keep PREVYMIS in its original package until you are ready to take it. Keep PREVYMIS and all medicines safely away from children.

Disposal

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 protect the environment.

Product Description

What it looks like

PREVYMIS is a film coated tablet.

240 mg: Yellow, oval shaped tablet debossed with “591” on one side and corporate logo on the other side

480 mg: Pink, oval, bi-convex, tablet debossed with “595” on one side and corporate logo on the other side

The tablets are packaged into a carton containing four (4) 7-count Polyamide/Aluminium/PVC – Aluminium blister cards for a total of 28 tablets.

Ingredients

PREVYMIS is available as 240 mg and 480 mg tablets.

- Active Ingredient

PREVYMIS tablets contain either 240 mg or 480 mg of Letermovir.

-Inactive Ingredients

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)

MAL number:

MAL19096014ARZ

MAL19096013ARZ

Manufacturer

MSD International GmbH
T/A MSD Ireland (Ballydine),
Kilsheelan, Clonmel,
Co. Tipperary, Ireland.

Packer

Organon Heist bv
Industriepark 30
2220 Heist-op-den-Berg
Belgium

Product Registration Holder

Merck Sharp & Dohme (Malaysia)
Sdn. Bhd.
Lot No. B-22-1 & B-22-2, Level 22
The Ascent, Paradigm No. 1
Jalan SS 7/26A, Kelana Jaya
47301 Petaling Jaya
Selangor, Malaysia

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