Product Name: Prevymis Tablets	Component: English Patient Information Leaflet Date Approved: 15 November 2022

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PREVYMIS® 240 mg Tablets

letermovir

Read all of this leaflet carefully before you start taking PREVYMIS because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare professional.
- PREVYMIS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
- If you get 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
2. What you need to know before you take PREVYMIS
3. How to take PREVYMIS
4. Possible side effects
5. How to store PREVYMIS
6. Contents of the pack and other information

1. What PREVYMIS is and what it is used for

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

PREVYMIS is a prescription 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 PREVYMIS (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 the above applies 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.

Report any muscle pain or tenderness while taking a statin.

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

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional 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 “Do not take PREVYMIS if”.

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.

Human reproduction

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking PREVYMIS. PREVYMIS is not recommended during pregnancy or in women of childbearing potential not using contraception.

Breastfeeding

Mothers receiving PREVYMIS should not breastfeed their babies.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking PREVYMIS.

Driving and using machines

PREVYMIS may have an 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 Tablets contain 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

PREVYMIS contains less than 1 mmoL sodium (23 mg) per 240 mg tablet, that is to say essentially “sodium-free”.

3. How to take PREVYMIS

Always take PREVYMIS 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 two 240 mg tablets 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(s) whole with water. Do not break, crush or chew the tablet(s).

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 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 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 PREVYMIS, ask your doctor, pharmacist or nurse.

4. Possible side effects

PREVYMIS can cause side effects.

Not all side effects reported for PREVYMIS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PREVYMIS, please consult your doctor, pharmacist or other healthcare professionals for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- allergic reaction (hypersensitivity) – the signs may include wheezing, difficulty breathing, rashes or hives, itchiness, swelling.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- diarrhoea
- feeling sick (nausea)
- being sick (vomiting).

Less frequent:

- 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PREVYMIS.

5. How to store PREVYMIS

Store all medicines out of reach of children.

Do not use PREVYMIS 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.

Store at or below 30 °C. 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 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.

The other ingredients are:

Tablet core: microcrystalline cellulose (E460); croscarmellose sodium (E468); povidone (E1201); colloidal anhydrous silica (E551) and magnesium stearate (E470b).

Film-coating: lactose monohydrate; hypromellose (E464); titanium dioxide (E171); triacetin (E1518); iron oxide yellow (E172) and carnauba wax (E903).

What PREVYMIS looks like and contents of the pack

PREVYMIS 240 mg Tablets

PREVYMIS 240 mg 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.

Holder of Certificate of Registration

MSD (Pty) Ltd, 117 16th Road, Halfway House 1685, South Africa

Tel. No.: 011 655 3000

This leaflet was last revised on

Registration Number

54/20.2.8/0429