PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PREVYMIS® 240 mg Concentration for Solution for Infusion

letermovir

Read all of this leaflet carefully before you are given 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.
- 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

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 are given PREVYMIS

You should not be given 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*).

You should not be given PREVYMIS if the above applies to you. If you are not sure, talk to your doctor, pharmacist or nurse before you are given 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 “You should not be given 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 contains sodium

PREVYMIS contains sodium. If you are on a low sodium diet, talk to your doctor before you are given PREVYMIS.

Each 240 mg vial contains 23 mg sodium (main component of cooking/table salt). This is equivalent to 1,15 % of the recommended maximum daily dietary intake of sodium for an adult.

PREVYMIS contains cyclodextrin

Each 240 mg dose (12 mL vial) of PREVYMIS contains 1 800 mg cyclodextrin.

If you have a kidney disease, talk to your doctor before you receive PREVYMIS.

3. How you are given PREVYMIS

The recommended dose of PREVYMIS is 480 mg once a day. If you also take ciclosporin, your doctor will decrease the dose of PREVYMIS to 240 mg once a day.

You will get PREVYMIS as an infusion (drip) into a vein and it will take about 1 hour. You will get PREVYMIS once a day.

If you are given more PREVYMIS than you should

If you think you have been given too much PREVYMIS, tell your doctor straight away.

If you miss your appointment to get PREVYMIS

It is important that you do not miss or skip doses of PREVYMIS.

- If you miss your appointment to get PREVYMIS, call your doctor straight away to reschedule your appointment.

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

Store at or below 25 °C. Store in the original carton to protect from light.

Chemical and physical in-use stability has been demonstrated for 48 hours at 25 °C and for 48 hours at 2 to 8 °C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

Any unused portion of the infusion solution should be discarded.

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 vial contains 240 mg letermovir. Each mL of concentrate contains 20 mg.

The other ingredients are: hydroxypropylbetadex (cyclodextrin); sodium chloride; sodium hydroxide (E524) and water for injections.

What PREVYMIS looks like and contents of the pack

PREVYMIS 240 mg Concentrate for Solution for Infusion is a clear, colourless liquid and may contain a few product-related small translucent or white particles.

The 240 mg concentrate for solution for infusion is packaged in clear, glass vials. Each vial is packaged in a carton.

Holder of Certificate of Registration

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