Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PREVYMIS®

letermovir tablets
letermovir for injection

This Patient Medication Information is written for the person who will be taking **PREVYMIS®**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **PREVYMIS®**, talk to a healthcare professional.

What PREVYMIS® is used for:

PREVYMIS® is a prescription medicine to help prevent getting ill from CMV (cytomegalovirus). CMV is a virus. For most people, CMV doesn't hurt them. However, if your immune system is weak after you get an allogeneic hematopoietic stem cell (bone marrow) transplant or a kidney transplant, you may be at high risk of becoming ill from CMV. PREVYMIS® is used in:

- adults and children 12 years of age and older who weigh at least 30 kg, after receiving an allogenic hematopoietic stem cell (bone marrow) transplant.
- adults and children 12 years of age and older who weigh at least 40 kg, after receiving a kidney transplant.

How PREVYMIS® works:

PREVYMIS® is an antiviral medicine. It stops CMV from multiplying.

The ingredients in PREVYMIS® are:

Medicinal ingredient: letermovir

Non-medicinal ingredients: Tablets: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose and povidone 25.

The tablets are film-coated with a coating material containing the following inactive ingredients: hypromellose 2910, iron oxide yellow, and (only for 480 mg tablets) iron oxide red, lactose monohydrate, titanium dioxide and triacetin. Carnauba wax is added as a polishing agent.

Injection (IV): hydroxypropyl betadex, sodium chloride, sodium hydroxide, and Water for Injection.

PREVYMIS® comes in the following dosage forms:

Tablet: 240 mg and 480 mg
Solution for injection: 20 mg/mL. Available in 240 mg/12 mL and 480 mg/24 mL

Do not use PREVYMIS® if you:

- are allergic to letermovir, or any of the other ingredients of PREVYMIS®.

- are taking any of the following medicines:
  - Pimozide (for Tourette's syndrome).
  - Ergot alkaloids (for migraine headaches).

If you are taking PREVYMIS® with cyclosporine, do not take lovastatin, rosuvastatin, simvastatin, or bosentan.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PREVYMIS®. Talk about any health conditions or problems you may have, including if you:

- have kidney disease.
- have liver disease.
- are a pregnant woman or trying to get pregnant. It is not known if PREVYMIS® will harm your baby while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if PREVYMIS® gets in your breast milk and will be passed to your baby.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with PREVYMIS®:

- If you take any of these medicines, be sure to tell your doctor:
  - Alfentanil, fentanyl (for severe pain)
  - Amiodarone (used to correct irregular heartbeats)
  - Midazolam (used as a sedative)
  - Cyclosporine, tacrolimus, sirolimus (used to prevent transplant rejection)
  - Voriconazole (for fungal infections)
  - Statins, such as atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin (for high cholesterol)
  - Omeprazole, pantoprazole (for stomach ulcers and other stomach problems)
  - Glyburide, repaglinide, rosiglitazone (for high blood sugar)
  - Carbamazepine, phenobarbital, phenytoin (for seizures or convulsions)
  - Warfarin (used as a blood thinner or for blood clots)
  - Rifabutin, rifampin (for mycobacterial infections)
  - Bosentan (for high blood pressure in the vessels of the lungs)
  - St. John's wort (*Hypericum perforatum*) (an herbal product)
  - Efavirenz, etravirine, nevirapine (for HIV)
  - Modafinil (for wakefulness)
- Know the medicines you take. Keep a list of medicines and show it to your doctor and pharmacist when you get a new medicine.
- You can ask your doctor or pharmacist for a list of medicines that may interact with PREVYMIS®.
- Do not start or stop taking another medicine without telling your doctor first.

How to take PREVYMIS®:

- You can receive PREVYMIS® two different ways: as tablets or through an IV (intravenously).
- It is important that you do not miss or skip doses of PREVYMIS®.

Usual dose:

If you take the tablets:

- **Take as directed once a day.**
  - Take at the same time every day.
  - Take with or without food.
  - Swallow the tablet whole. Do not break, crush, or chew the tablet.
- Take this medicine exactly how your doctor tells you to take it.
- Keep it in the original package until you are ready to take it.
- Do not stop taking PREVYMIS® without talking to your doctor first.
- Do not run out of your PREVYMIS®.

If you receive PREVYMIS® through an IV (intravenously):

- You will receive PREVYMIS® once a day and it will take about 1 hour.

Overdose:

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

If you think you, or a person you are caring for, have taken too much PREVYMIS®, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you take the tablets:

If you forget to take your dose of PREVYMIS®, take it as soon as you remember.
If you do not remember until it is almost time for your next dose, skip your last dose and take the next dose at your 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 receive PREVYMIS® through an IV (intravenously):

- If you miss your appointment, reschedule it right away.

Possible side effects from using PREVYMIS®:

These are not all the possible side effects you may have when taking PREVYMIS®. If you experience any side effects not listed here, tell your healthcare professional.

Common side effects of PREVYMIS®:

- nausea
- diarrhea
- vomiting

Serious side effects and what to do about them

Symptom/effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Common			
Leukopenia / Neutropenia (low number of white blood cells (cells that fight infection)): fatigue, fever, aches, pains and flu-like symptoms		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Tablet and solution for injection:

- Keep PREVYMIS® in the original package until you are ready to take it.
- Keep PREVYMIS® tablets at room temperature (15°C to 30°C).
- If you have to keep PREVYMIS® injection at home, keep it at room temperature (15°C to 25°C). Protect from light.

Keep out of reach and sight of children.

If you want more information about PREVYMIS®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website (www.merck.ca); or by calling 1-800-567-2594.

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