

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

 **PREVYMIS[®]**
letermovir tablets
letermovir for injection

Read this carefully before you start taking **PREVYMIS[®] (letermovir)** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PREVYMIS[®]**.

What is PREVYMIS[®] used for?

PREVYMIS[®] is a prescription medicine to help to keep adults 18 years of age and older from getting ill from CMV (cytomegalovirus). CMV is a virus that a lot of people have, but they don't even know it. For most people, CMV just stays in their body and it doesn't 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.

How does PREVYMIS[®] work?

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

What are the ingredients in PREVYMIS[®]?

Medicinal ingredients: letermovir

PREVYMIS[®] is available as either a tablet or an IV

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 women 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 adult dose:**If you take the tablets:**

- **Take 1 tablet once a day.**
 - Take it at the same time every day.
 - Take it 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 have taken too much PREVYMIS®, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:**If you forget to 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.

What are possible side effects from using PREVYMIS®?

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

Common side effects of PREVYMIS®:

- nausea
- diarrhea
- vomiting

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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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 this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>) or the Merck Canada website (www.merck.ca) or by calling Merck Canada at 1-800-567-2594.

To report an adverse event related to PREVYMIS®, please contact 1-800-567-2594.

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