

Patient Information
PREVYMIS™ (PREH-vih-miss)
(letermovir) tablets
(letermovir) injection, for intravenous use

What is PREVYMIS?

PREVYMIS is a prescription medicine to help to prevent cytomegalovirus (CMV) infection and disease in adults who have received an allogeneic hematopoietic stem cell (bone marrow) transplant.

It is not known if PREVYMIS is safe and effective in children under 18 years of age.

Who should not take PREVYMIS?

Do not take PREVYMIS if you take:

- Pimozide
- Ergot alkaloids

If you are taking PREVYMIS with cyclosporine, do not take:

- Pitavastatin or simvastatin

What should I tell my doctor before taking PREVYMIS?

Tell your doctor about all your medical conditions, including if you:

- Have kidney or liver problems.
- Are pregnant or plan to become pregnant. It is not known if PREVYMIS will harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if PREVYMIS passes into your breast milk. Talk to your doctor about the best way to feed your baby while taking PREVYMIS.

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. PREVYMIS may affect the way other medicines work, and other medicines may affect how PREVYMIS works and cause serious side effects.

Know the medicines you take. Keep a list of medicines and show it to your doctor and pharmacist when you get a new medicine. Your doctor or pharmacist will tell you if it is safe to take PREVYMIS with other medicines. Do not start or stop taking another medicine without telling your doctor first.

How should I take PREVYMIS?

PREVYMIS comes as a tablet or can be given by your doctor through an IV line (intravenously).

- **If you take PREVYMIS tablets:**

- Take PREVYMIS exactly as your doctor tells you to take it. Do not stop taking PREVYMIS without talking to your doctor first.
- Take 1 PREVYMIS tablet once a day.
- Take PREVYMIS with or without food.
- Swallow PREVYMIS tablets whole.
- It is important that you do not miss or skip doses of PREVYMIS.
- If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and take your dose at the next scheduled time. Do not take 2 doses of PREVYMIS at the same time to make up for a missed dose.
- If you take too much PREVYMIS, call your doctor right away.

- **If you receive PREVYMIS through an IV line (intravenously):**

- You will receive PREVYMIS 1 time each day given over 1 hour.
- If you miss or skip your dose of PREVYMIS, call your doctor right away.

What are the possible side effects of PREVYMIS?

The most common side effects while taking PREVYMIS include:

- nausea
- diarrhea
- vomiting
- swelling in your arms and legs
- cough
- headache
- tiredness
- stomach (abdominal) pain

These are not all the possible side effects of PREVYMIS.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store PREVYMIS?

- Store PREVYMIS tablets and PREVYMIS injection at room temperature between 68°F to 77°F (20°C to 25°C).
- Store PREVYMIS tablets in the original package until you are ready to take it.
- Store PREVYMIS injection in the original carton to protect from exposure to light.

Keep PREVYMIS and all medicines out of the reach of children.

General information about the safe and effective use of PREVYMIS

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not use PREVYMIS for a condition for which it was not prescribed. Do not give PREVYMIS to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about PREVYMIS that is written for healthcare professionals.

What are the ingredients in PREVYMIS?

Active ingredient: letermovir

Inactive ingredients:

Tablets: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, and povidone 25. **Film coating:** hypromellose 2910, iron oxide red (only for 480 mg tablets), iron oxide yellow, lactose monohydrate, titanium dioxide, triacetin. Carnauba wax is added as a polishing agent.

Injection: hydroxypropyl betadex, sodium chloride, sodium hydroxide, and Water for Injection, USP.

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For more information go to www.PREVYMIS.com or call 1-800-444-2080.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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