

Patient Information		
PREVMIS® (PREH-vih-miss) (letermovir) tablets	PREVMIS® (PREH-vih-miss) (letermovir) oral pellets	PREVMIS® (PREH-vih-miss) (letermovir) injection, for intravenous use

What is PREVMIS?

PREVMIS is a prescription medicine used to help prevent:

- cytomegalovirus (CMV) infection and disease in adults and children 6 months and older weighing at least 13.2 pounds (lbs) or 6 kilograms (kg) who:
 - have received an allogeneic hematopoietic stem cell (bone marrow) transplant, **and**
 - have a high risk for getting CMV infection and disease.
- CMV disease in adults and children 12 years of age and older weighing at least 88.2 lbs (40 kg) who:
 - have received a kidney transplant, **and**
 - have a high risk for getting CMV disease.

It is not known if PREVMIS is safe and effective in:

- children under 6 months of age or weighing less than 13.2 lbs (6 kg) who received a hematopoietic stem cell transplant, **or**
- children under 12 years of age or weighing less than 88.2 lbs (40 kg) who received a kidney transplant.

Who should not take PREVMIS?

Do not take PREVMIS if you take:

- pimozide
- ergot alkaloids

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

- pitavastatin or simvastatin

What should I tell my healthcare provider before taking PREVMIS?

Before taking PREVMIS, tell your healthcare provider 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 PREVMIS will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if PREVMIS passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking PREVMIS.

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

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

How should I take PREVMIS?

- PREVMIS comes as a tablet, oral pellets, or can be given by your healthcare provider through an IV line (intravenously).
- PREVMIS given intravenously should be used only if you are unable to take PREVMIS tablets or PREVMIS oral pellets. You should switch to PREVMIS tablets or PREVMIS oral pellets as soon as you are able to.

- Take PREVYMIS tablets or oral pellets exactly as your healthcare provider tells you to take it. Do not stop taking PREVYMIS without talking to your healthcare provider first.
- Take PREVYMIS tablets or oral pellets 1 time a day.
- It is important that you do not miss or skip doses of PREVYMIS.
- If you miss a dose of PREVYMIS tablets or oral pellets, 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 or take more than your prescribed dose to make up for a missed dose.
- If you take too much PREVYMIS tablets or oral pellets, call your healthcare provider right away.
- **If you take PREVYMIS tablets:**
 - Take PREVYMIS with or without food.
 - Swallow PREVYMIS tablets whole.
- **If you take PREVYMIS oral pellets:**
 - Your healthcare provider will tell you the number of PREVYMIS oral pellet packets to take for your prescribed dose.
 - PREVYMIS oral pellets can be taken by mouth after mixing with soft food or given through a nasogastric tube (NG tube) or gastric tube (G tube).
 - **See the Instructions for Use for the right way to prepare and take a dose of PREVYMIS oral pellets.** Keep the Instructions for Use and follow it each time you prepare and take PREVYMIS oral pellets.
 - Do not crush or chew PREVYMIS oral pellets.
- **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 healthcare provider right away.

What are the possible side effects of PREVYMIS?

The most common side effects of PREVYMIS in adults who have received a hematopoietic stem cell transplant include:

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

The most common side effect of PREVYMIS in adults who have received a kidney transplant is diarrhea.

The side effects of PREVYMIS in children are similar to the side effects in adults.

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, PREVYMIS oral pellets, 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 to protect from moisture.
- Store PREVYMIS oral pellets in the original packet until you are ready to take them.
- 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, and triacetin. Carnauba wax is added as a polishing agent.

Oral Pellets: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, and povidone K-29/32.

Film coating: hypromellose 2910, iron oxide red, iron oxide yellow, lactose monohydrate, titanium dioxide, and triacetin.

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

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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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