

▼ This medicine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

PREVMIS®

Letermovir

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PREVMIS. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PREVMIS against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What PREVMIS is used for

PREVMIS is a medicine to help to keep you from getting sick from CMV (cytomegalovirus) in adults who have recently had a bone marrow transplant. PREVMIS works by preventing the body from making more CMV.

CMV is a virus. It's 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.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

Before you take PREVMIS

When you must not take it

Do not take PREVMIS if you:

- are allergic to letermovir or any of the other ingredients of PREVMIS.
- are taking any of the following medicines:
 - Pimozide (for Tourette's syndrome)
 - Ergot alkaloids (for migraine headaches)

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

- Pitavastatin or simvastatin

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or trouble breathing.

Do not take PREVMIS if the packaging is torn or shows signs of tampering.

Do not take PREVMIS if the expiry date printed on the pack has passed.

It is not known if PREVMIS is safe and effective for people under 18 years old.

Before you start to take it

Tell your doctor if:

1. you are allergic to any other medicines, foods, dyes or preservatives
2. you are pregnant or plan to become pregnant.

It is not known if PREVMIS will harm your baby while you are pregnant. Your doctor will discuss the risks and benefits of taking PREVMIS when pregnant.

3. you are breastfeeding or planning to breastfeed.

It is not known if PREVMIS gets in your breast milk and will be passed to your baby. Your doctor will discuss the risks and benefits of taking PREVMIS whilst breastfeeding.

If you have not told your doctor about any of the above, tell them before you take PREVMIS.

Taking other medicines

Tell your doctor 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.

Your doctor or pharmacist will tell you if it is safe to take PREVYMIS with other medicines.

Know the medicines you take. Keep a list of medicines and show it to your doctor and pharmacist when you get a new medicine.

There are some medicines you must not take with PREVYMIS. See list under "Before you take PREVYMIS/When you must not take it"

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, fentanyl (for severe pain)
- amiodarone - used to correct irregular heartbeats
- midazolam - used as a sedative
- quinidine (for abnormal heart rhythms)
- ciclosporin, tacrolimus, sirolimus (used to prevent transplant rejection)
- voriconazole (for fungal infections)
- statins, such as atorvastatin, pitavastatin, simvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin (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)
- nafcillin (for bacterial infections)
- rifabutin, rifampicin (for bacterial infections, including tuberculosis)
- thioridazine (for psychiatric disorders)

- bosentan (for high blood pressure)
- St. John's wort (Hypericum perforatum) - a herbal product
- efavirenz, etravirine, nevirapine (for HIV)
- modafinil (for wakefulness)

Your doctor will tell you what to do if you are taking any of these medicines.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking PREVYMIS

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist. Do not start or stop taking another medicine without telling your doctor first.

How to take PREVYMIS

Take this medicine exactly how your doctor tells you to take it. You can receive PREVYMIS two different ways: as tablets or through an IV (intravenously).

How much to take

If you take the tablets:

- **Take 1 tablet once a day.**

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

If you receive PREVYMIS through an IV (intravenously):

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

When to take it

If you take the tablets:

- **Take PREVYMIS at about the same time each day.**

Your doctor will tell you when to take your tablets.

How to take it

If you take the tablets:

- **Swallow the tablet whole. Do not break, crush, or chew the tablet. Take it with or without food.**

How long to take it

Keep taking PREVYMIS until your doctor tells you to stop.

If you forget to take it

If you forget to take the tablets:

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

If you receive PREVYMIS through an IV (intravenously):

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken too much PREVYMIS. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking PREVYMIS

Things you must do

Tell your doctor if you become pregnant while taking this medicine.

Tell your doctor if for any reason you have not taken your medicine exactly as prescribed.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Before starting any new medicine, tell your doctor or pharmacist that you are taking PREVYMIS .

Tell all doctors, dentists and pharmacists who are treating you that you are taking PREVYMIS .

Things you must not do

Do not suddenly stop taking PREVYMIS, or lower the dose, without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not stop taking PREVYMIS without talking to your doctor first. Never give it to anyone else.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PREVYMIS .

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask your doctor or pharmacist any questions you may have.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor if you notice any of the following and they bother you:

- nausea
- diarrhoea
- vomiting
- swelling in your arms and legs
- cough
- headache
- tiredness

- stomach (abdominal) pain

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you don't understand anything in this list.

After taking PREVYMIS

Storage

Keep your tablets in their blister pack until it is time to take them.

The tablets may not keep as well if you take them out of the blister pack.

Store PREVYMIS tablets below 30°C.

Store PREVYMIS concentrated injection for infusion vials below 25°C; limited excursions permitted between 15°C to 30°C. Store in the original carton to protect from light.

Do not store PREVYMIS , or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on window sills.

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Disposal

Return any unused medicine to your pharmacist.

Medicines should not be disposed of via waste water or household waste.

Product Description

What it looks like

The film-coated tablet of PREVYMIS (letermovir) is available in two strengths: 240mg and 480mg.

The 240 mg tablet is a yellow oval tablet. Each tablet is debossed with "591" on one side and MSD logo on the other side.

The 480 mg tablet is a pink oval, bi-convex tablet. Each tablet is debossed with "595" on one side and MSD logo on the other side.

Pack size: blister packs of 28 film-coated tablets.

PREVYMIS is also available as a single-dose vial that will be mixed with a solution and given as an IV. The vial will contain 240 mg/12 mL or 480 mg/24 mL of letermovir as the active ingredient.

Not all products supplied.

Ingredients

PREVYMIS tablets contain the following inactive ingredients:

- microcrystalline cellulose
- croscarmellose sodium
- povidone
- silicon dioxide
- magnesium stearate
- lactose monohydrate
- hypromellose
- titanium dioxide
- triacetin
- iron oxide yellow
- carnauba wax

The 480 mg oval PREVYMIS tablets also contains the following inactive ingredient:

- iron oxide red

PREVYMIS concentrated injection for infusion contains the following inactive ingredients:

- hydroxypropylbetadex
- sodium chloride
- sodium hydroxide

- Water for Injections

Sponsor

PREVYMIS is supplied in Australia
by:

Merck Sharp & Dohme (Australia)
Pty Limited

Level 1, Building A,

26 Talavera Road,

Macquarie Park, NSW 2113,

Australia

Australian Registration Numbers

AUST R 289794 - 240 mg/12 mL
concentrated injection for infusion

AUST R 289795 - 240 mg tablets

AUST R 289796 - 480 mg/24 mL
concentrated injection for infusion

AUST R 289797 - 480 mg tablets

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