

# PREVYMIS®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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▼ Please report side effects. See the [full CMI](#) for further details.

## 1. Why am I using PREVYMIS?

PREVYMIS contains the active ingredient letermovir. PREVYMIS is used to help keep you from getting sick from CMV (cytomegalovirus) in adults who have recently had a bone marrow transplant. PREVYMIS works by preventing the body from making more CMV. For more information, see Section [1. Why am I using PREVYMIS?](#) in the full CMI.

## 2. What should I know before I use PREVYMIS?

Do not use if you have ever had an allergic reaction to letermovir or any of the ingredients listed at the end of the CMI. Do not use PREVYMIS if you are taking pimozide or ergot alkaloids. Do not use pitavastatin or simvastatin if you are taking PREVYMIS with

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ciclosporin. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding or plan to breastfeed.** For more information, see Section [2. What should I know before I use PREVYMIS?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with PREVYMIS and affect how it works. PREVYMIS may affect the way other medicines work. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use PREVYMIS?**

**If you take the tablets:**

- Take 1 tablet once a day.
- Swallow the tablet whole. Do not break, crush, or chew the tablet. Take it with or without food.
- Take PREVYMIS at about the same time each day.
- Your doctor will tell you when to take your tablets.

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

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

More instructions can be found in Section [4. How do I use PREVYMIS?](#) in the full CMI.

## 5. What should I know while using PREVYMIS?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>● Tell your doctor if you become pregnant while taking this medicine.</li><li>● Tell your doctor if for any reason you have not taken your medicine exactly as prescribed.</li><li>● Remind any doctor, dentist or pharmacist you visit that you are using PREVYMIS.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>● Do not stop taking PREVY MIS, or lower the dose, without first checking with your doctor.</li><li>● Never give PREVYMIS to anyone else.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>● Store PREVYMIS tablets below 30°C. The tablets may not keep as well if you take them out of the blister pack.</li><li>● Store PREVYMIS concentrated injection for infusion vials below</li></ul>

25°C. Store in the original carton to protect from light.

- Follow the instructions in the package on how to take care of your medicine properly.

For more information, see Section [5. What should I know while using PREVYMIS?](#) in the full CMI.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. The most common side effects of PREVYMIS are nausea, diarrhoea, vomiting, swelling in your arms and legs, cough, headache, tiredness and stomach (abdominal) pain.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. 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](http://www.tga.gov.au/reporting-problems).

## PREVYMIS®

**Active ingredient:** *letermovir*

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### Consumer Medicine Information (CMI)

This leaflet provides important information about using PREVYMIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PREVYMIS.**

**Where to find information in this leaflet:**

- [1. Why am I using PREVYMIS?](#)
- [2. What should I know before I use PREVYMIS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use PREVYMIS?](#)
- [5. What should I know while using PREVYMIS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I using PREVYMIS?**

**PREVYMIS contains the active ingredient letermovir.**

**PREVYMIS is used to help keep you from getting sick from CMV (cytomegalovirus) in adults who have recently had a bone marrow transplant. PREVYMIS 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.

## **2. What should I know before I use PREVYMIS?**

### **Warnings**

**Do not use PREVYMIS if:**

- **you are allergic to letermovir, or any of the ingredients listed at the end of this leaflet.**

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.

- **Always check the ingredients to make sure you can use this medicine.**
- **are taking any of the following medicines:**
  - Pimozide (for Tourette's syndrome)
  - Ergot alkaloids (for migraine headaches)
- **If you are taking PREVYMIS with ciclosporin, do not take:**
  - Pitavastatin or simvastatin
- **Do not take PREVYMIS if the packaging is torn or shows signs of tampering.**
- **Do not take PREVYMIS if the expiry date printed on the pack has passed.**

### **Check with your doctor if you:**

- **are allergic to any other medicines, foods, dyes or preservatives**
- **have any other medical conditions**
- **take any medicines for any other condition**
- **are pregnant or plan to become pregnant**
- **are breastfeeding or planning to breastfeed**

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

## **Children and adolescents**

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

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.



There are some medicines you must not take with PREVYMIS. See list under Section [2. What should I know before I use PREVYMIS?](#)

**Some medicines may interfere with PREVYMIS and affect how it works. PREVYMIS may affect the way other medicines work.**

- 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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PREVYMIS.**

## **4. How do I use 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 to take PREVYMIS**

#### **If you take the tablets:**

- Take 1 tablet once a day.
- Swallow the tablet whole. Do not break, crush, or chew the tablet. Take it with or without food.
- Take PREVYMIS at about the same time each day.
- Your doctor will tell you when to take your tablets.

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.

## **How long to take PREVYMIS**

Keep taking PREVYMIS until your doctor tells you to stop.

## **If you forget to take PREVYMIS**

### **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 use too much PREVYMIS**

If you think that you have used too much PREVYMIS, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using PREVYMIS?**

### **Things you should do**

#### **Call your doctor straight away if you:**

- become pregnant while taking this medicine.
- have not taken your medicine exactly as prescribed for any reason.

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

**Remind any doctor, dentist or pharmacist you visit that you are using PREVYMIS.**

### **Things you should not do**

- Do not stop taking PREVY MIS, or lower the dose, without first checking with your doctor.
- Never give PREVYMIS to anyone else.

### **Looking after your medicine**

- Store PREVYMIS tablets below 30°C.

- 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 concentrated injection for infusion vials below 25°C. Store in the original carton to protect from light.

Follow the instructions in the package on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

<b>Common side effects</b>	<b>What to do</b>
<p>Tell your doctor if you notice any of the following and they bother you:</p> <ul style="list-style-type: none"><li>• nausea</li><li>• diarrhoea</li><li>• vomiting</li><li>• swelling in your arms and legs</li><li>• cough</li><li>• headache</li><li>• tiredness</li><li>• stomach (abdominal) pain</li></ul>	<p><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side

effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

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

### **What PREVYMIS Tablet contains**

<b>Active ingredient (main ingredient)</b>	letermovir
<b>Other ingredients (inactive ingredients)</b>	microcrystalline cellulose croscarmellose sodium povidone silicon dioxide magnesium stearate lactose monohydrate hypromellose titanium dioxide triacetin iron oxide yellow carnauba wax

	<p>The 480 mg oval PREVYMIS tablets also contains the following inactive ingredient:</p> <p>iron oxide red</p>
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## What PREVYMIS Concentrated Injection for Infusion contains

<b>Active ingredient (main ingredient)</b>	letermovir
<b>Other ingredients (inactive ingredients)</b>	<p>hydroxypropylbetadex</p> <p>sodium chloride</p> <p>sodium hydroxide</p> <p>water for Injections</p>

Do not take this medicine if you are allergic to any of these ingredients.

## What PREVYMIS looks like

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

**PREVYMIS 240 mg tablet** is a yellow oval tablet. Each tablet is debossed with “591” on one side and MSD logo on the other side (AUST R 289795).



**PREVYMIS 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 (AUST R 289797).

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.

**PREVYMIS 240 mg/12 mL concentrated injection for infusion** (AUST R 289794).

**PREVYMIS 480 mg/24 mL concentrated injection for infusion** (AUST R 289796).

## **Who distributes PREVYMIS**

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road,

Macquarie Park, NSW 2113, Australia

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