

# Ganciclovir Lupin

## 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.

### 1. Why am I using Ganciclovir Lupin?

Ganciclovir Lupin contains the active ingredient ganciclovir. Ganciclovir Lupin is used to act against a certain type of herpes virus called cytomegalovirus or CMV. Ganciclovir Lupin is used to control CMV eye infections in AIDS patients, in treatment of CMV lung infections and in prevention of CMV infection and disease in patients following bone marrow or solid organ transplantation.

For more information, see Section [1. Why am I using Ganciclovir Lupin?](#) in the full CMI.

### 2. What should I know before I use Ganciclovir Lupin?

Do not use if you have ever had an allergic reaction to ganciclovir or any of the ingredients listed at the end of the CMI. Animal and other laboratory studies have shown Ganciclovir Lupin has caused infertility, birth defects and cancer. It is possible that these effects may also occur in humans.

**Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Ganciclovir Lupin?](#) in the full CMI.

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

Some medicines may interfere with Ganciclovir Lupin and affect how it works.

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 Ganciclovir Lupin?

- Ganciclovir Lupin is added to an infusion bag and given as a 'drip' into a vein, usually over a period of one hour.
- Ganciclovir Lupin is usually given once or twice a day at a dose determined by your doctor in consideration of your kidney function and severity of your infection.

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

### 5. What should I know while using Ganciclovir Lupin?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Ganciclovir Lupin.</li><li>• See your doctor regularly for careful monitoring of your CMV disease, blood cell counts and other potential side effects. CMV eye conditions require close monitoring of the retina.</li><li>• Inform your doctor if you become pregnant while receiving Ganciclovir Lupin. You must use a reliable form of contraception during Ganciclovir Lupin therapy, and for at least 30 days after stopping Ganciclovir Lupin.</li><li>• If there is a possibility of your partner becoming pregnant, a barrier contraceptive should be used while receiving Ganciclovir Lupin and for 90 days after stopping.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take any other medicines whether they require a prescription or not, without first telling your doctor or consulting a pharmacist.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Ganciclovir Lupin may cause drowsiness, dizziness, confusion or seizures (fits) in some people and affect alertness. Make sure you know how you react to Ganciclovir Lupin before you drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or not alert.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Ganciclovir Lupin vials and infusion bags will be stored in the pharmacy or on the ward.</li></ul>

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

### 6. Are there any side effects?

Many unwanted effects commonly reported in people with HIV appear related to their medical condition. See your doctor regularly so that your CMV disease, blood cell counts and any other potential side effects may be monitored carefully.

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.

# Ganciclovir Lupin

**Active ingredient(s):** ganciclovir

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Ganciclovir Lupin. **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 Ganciclovir Lupin.**

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

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

## 1. Why am I using Ganciclovir Lupin?

**Ganciclovir Lupin contains the active ingredient ganciclovir.** Ganciclovir Lupin belongs to a class of medicines used to treat viral infections. It works by stopping certain viruses from growing in the body.

Ganciclovir Lupin acts against a certain type of herpes virus called cytomegalovirus or CMV. CMV causes infections mainly in people with poor immunity. Poor immunity can be caused by HIV/AIDS or some transplant medications.

**Ganciclovir Lupin is used to control CMV eye infections in AIDS patients and in other patients who have poor immunity, which if left untreated can cause blindness.**

Ganciclovir Lupin is not a cure for CMV eye infections and is not effective against any underlying HIV-infection.

**Ganciclovir Lupin may also be used to treat CMV lung infections in bone marrow transplant patients or in prevention of CMV infection and disease in patients following bone marrow or solid organ transplantation.**

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

Your doctor, however, may have prescribed Ganciclovir Lupin for another purpose.

Ganciclovir Lupin is not addictive.

## 2. What should I know before I use Ganciclovir Lupin?

### Warnings

Animal and other laboratory studies have shown Ganciclovir Lupin has caused infertility, birth defects and

cancer. It is possible that these effects may also occur in humans.

### Do not use Ganciclovir Lupin if:

- you are allergic to ganciclovir, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have had an allergic reaction to Ganciclovir Lupin or Vitrasert® implant, or other drugs from the same family, eg. valganciclovir (Valcyte®); aciclovir (Zovirax®, Acyclo-V®, Acihexal®, Lovir® or Zyclir®); valaciclovir (Valtrex®, Zelitrex®, Xerebid®, Valnir®). Some of the symptoms of an allergic reaction may include:
  - shortness of breath, wheezing or difficulty breathing;
  - swelling of the face, lips, tongue or other parts of the body;
  - rash, itching or hives on the skin.
- you have very low blood counts for platelets (which help clotting) or neutrophils (a type of white blood cell which defends against infection) or haemoglobin (a substance that carries oxygen in the blood)
- you are pregnant.
- you are breastfeeding or intend to breastfeed.
- the package is torn or shows signs of tampering.
- the expiry date (EXP) printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well.

### Check with your doctor if you:

- have any other medical conditions including:
  - a history of low blood counts for platelets (thrombocytopenia), neutrophils (neutropenia) or red blood cells/haemoglobin (anaemia)
  - if you have, or previously have had, poor kidney function.
- are less than 12 years of age. There is very little information available on the use of Ganciclovir Lupin in children less than 12 years and safety and effectiveness in children has not been proven. Children that take Ganciclovir Lupin, when grown-up, have an increased risk of cancer and, also, adverse effects when trying to have children of their own. Therefore, Ganciclovir Lupin should only be used if these risks are outweighed by the benefits of treatment.

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.

Your baby may absorb this medicine in the womb and therefore there is a high likelihood of harm to the baby.

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

Ganciclovir Lupin may pass into breast milk and therefore there is a possibility that the breastfed baby may be affected.

## 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.

**Some medicines may interfere with Ganciclovir Lupin. These medicines include:**

- probenecid (eg. Benemid®);
- zidovudine (eg. AZT, Retrovir®, Combivir®);
- didanosine (eg. ddI or Videx®);
- imipenem/cilastatin (eg. Primaxin®);
- medicines for the treatment of cancer;
- other medicines for the treatment of HIV or HIV-related infections;
- mycophenolate mofetil (eg. CellCept®), a medicine used to prevent rejection of transplanted organs;
- other medicines used to prevent rejection of transplanted organs.

These medicines may be affected by Ganciclovir Lupin, or may affect how well it works. You may need to receive different amounts of your medicine, or you may need to receive different medicines. Your doctor will advise you.

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

## 4. How do I use Ganciclovir Lupin?

### How Ganciclovir Lupin is given

- Ganciclovir Lupin is added to an infusion bag and given as a 'drip' into a vein, usually over a period of one hour.
- Your doctor will decide what dose of Ganciclovir Lupin you will receive. This depends on how serious your infection is as well as your kidney function.

### When Ganciclovir Lupin is given

- Ganciclovir Lupin is usually given once or twice a day.

### If you use too much Ganciclovir Lupin

If you think that you have used too much Ganciclovir Lupin, you may need urgent medical attention, especially if you develop serious side effects listed in Section [6. Are there any side effects?](#)

### 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 Ganciclovir Lupin?

### Things you should do

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

- if you become pregnant while receiving Ganciclovir Lupin;
- develop any of the serious side effects listed in Section [6. Are there any side effects?](#)

Remind any doctor, dentist or pharmacist you visit that you are using Ganciclovir Lupin.

#### If you are a sexually active woman or man

- If you are a sexually active man, you should use condoms during and for at least 90 days following treatment with Ganciclovir Lupin unless it is certain that your female partner is not at risk of pregnancy.
- If you are a woman who could become pregnant and you are not using contraception, you must use a reliable form of contraception during Ganciclovir Lupin therapy, and for at least 30 days after stopping Ganciclovir Lupin, unless you are not sexually active.

### Things you should not do

- Do not take any other medicines whether they require a prescription or not, without first telling your doctor or consulting a pharmacist.

### You must see your doctor regularly

- See your doctor regularly so that your CMV disease, blood cell counts, and any other potential side effects may be monitored carefully.  
If blood cell counts are low then this may reduce your ability to fight infection, or for your blood to clot efficiently. If left undetected these effects on blood cells may contribute to death or serious illness.
- If you have a CMV eye infection, you must also see your doctor regularly to monitor the condition of your retina (part of the eye).

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Ganciclovir Lupin affects you.**

Ganciclovir Lupin may cause dizziness, confusion or seizures (fits) in some people and therefore may affect alertness. Make sure you know how you react to Ganciclovir Lupin before you drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

## Drinking alcohol

Tell your doctor if you drink alcohol.

## Looking after your medicine

- Ganciclovir Lupin vials and infusion bags will be stored in the pharmacy or on the ward.

## 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.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• Pain.</li><li>• Loss of feeling or tingling.</li><li>• Itching.</li><li>• Skin rash.</li><li>• Difficulty in swallowing.</li><li>• Cough.</li><li>• Nervousness or feeling anxious.</li><li>• Confusion.</li><li>• Headache.</li><li>• Fluid build-up.</li><li>• Indigestion.</li><li>• Shortness of breath.</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• A deterioration or worsening of your eyesight even if you are receiving Ganciclovir Lupin.</li><li>• Bruising or purple spots.</li><li>• Any sign of infection such as fever, chills, sore throat or mouth ulcers.</li><li>• Rapid or irregular heartbeat or sudden fevers.</li><li>• Tiredness.</li><li>• Severe allergic reactions causing swelling, rash or itching.</li><li>• Severe blisters and bleeding in the lips eyes, mouth, nose and genitals.</li><li>• Pain or inflammation in your chest, stomach or intestines.</li><li>• Bleeding (haemorrhage).</li><li>• Collapse, numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech.</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

Serious side effects	What to do
<ul style="list-style-type: none"><li>• Pain, swelling or joint stiffness.</li><li>• Seizures (fits).</li><li>• Change in the amount of urine you pass.</li></ul>	

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.

Many unwanted effects commonly reported in people with HIV appear to be related to their medical condition. The following list are unwanted effects seen in people receiving intravenous Ganciclovir Lupin which may or may not be caused by their medication.

### Side effects related to existing medical conditions

Side effects which may or may not be caused by Ganciclovir Lupin	What to do
<ul style="list-style-type: none"><li>• Low white blood cell counts.</li><li>• Anaemia (low red blood cell counts).</li><li>• Diarrhoea.</li><li>• Nausea and/or vomiting.</li><li>• Feeling of weakness.</li><li>• Weight loss.</li><li>• Low blood platelet count.</li><li>• Other infections.</li><li>• Injection site soreness or redness.</li></ul>	<b>Maintain regular doctor visits for monitoring of your medical condition especially during treatment with Ganciclovir Lupin.</b>

### 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 Ganciclovir Lupin contains

<b>Active ingredient (main ingredient)</b>	Ganciclovir
<b>Other ingredients (inactive ingredients)</b>	There are no other ingredients in Ganciclovir Lupin vials.

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

Ganciclovir Lupin does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

### **What Ganciclovir Lupin looks like**

Ganciclovir Lupin is available as a freeze-dried powder in clear glass vials (AUST R 280238). It will be made up into an infusion bag before being given to you.

### **Who distributes Ganciclovir Lupin**

#### **SPONSOR**

Southern Cross Pharma Pty Ltd

Suite 2, Level 2

19-23 Prospect Street

Box Hill, VIC, 3128

Australia

#### **Distributor**

Generic Health Pty Ltd

Suite 2, Level 2

19-23 Prospect Street

Box Hill, VIC, 3128

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This leaflet was prepared in September 2025.