

## 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 VALCYTE?

VALCYTE contains the active ingredient valganciclovir. VALCYTE acts against a virus called cytomegalovirus or CMV. VALCYTE is used to treat CMV eye infections in AIDS patients and to prevent CMV infection in patients following organ transplantation.

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

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

Do not use if you have ever had an allergic reaction to valganciclovir or any of the ingredients listed at the end of the CMI.

**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.**

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

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

Some medicines may interfere with VALCYTE 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 VALCYTE?

- Induction treatment for adults (for active CMV retinitis): 900mg twice daily with food for 21 days. Use the dispenser provided and take two 9 mL in the morning and in the evening.
- Maintenance treatment for adults (after induction treatment or for inactive CMV retinitis): 900mg once daily with food. Use the dispenser provided and take two 9 mL at the same time each day.
- Prevention of CMV disease in transplantation for adults: 900mg once daily with food, starting within 10 days post transplantation until 100 days post transplantation. If you have received a kidney transplant, the same daily dose is required until 200 days post transplantation. Use the dispenser provided to take two 9 mL at the same time each day.
- Prevention of CMV disease in transplantation for children: Your doctor will advise the appropriate dose.

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

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

<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 VALCYTE.</li><li>• Tell your doctor if you become pregnant while taking VALCYTE.</li><li>• See your doctor regularly so that your CMV disease and blood cell counts may be monitored.</li><li>• If you have a CMV eye infection, see your doctor regularly to monitor your retina (part of the eye).</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking VALCYTE or change the dosage without first checking with your doctor.</li><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>• Be careful driving or operating machinery until you know how VALCYTE affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep VALCYTE solution in the original bottle.</li><li>• Keep VALCYTE in the refrigerator (2-8°C). Do not freeze.</li></ul>

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

### 6. Are there any side effects?

Go to your nearest hospital if you experience: swelling of the tongue, lips or throat, any sign of infection such as fever, chills, sore throat or mouth ulcers, unexplained bruising or bleeding, hallucinations, confusion, agitation; or fits.

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.

# VALCYTE®

## Powder for Oral Solution

Active ingredient(s): valganciclovir

### Consumer Medicine Information (CMI)

This leaflet provides important information about using VALCYTE. **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 VALCYTE.**

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

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

### 1. Why am I using VALCYTE?

**VALCYTE contains the active ingredient valganciclovir.**

In the body valganciclovir rapidly changes to ganciclovir.

VALCYTE belongs to a group of medicines used to prevent the growth of viruses.

VALCYTE acts against a virus called cytomegalovirus or CMV (a type of herpes virus). It prevents this virus from growing and multiplying in the body.

CMV causes infections, mainly in people with poor immunity. Poor immunity can be caused by HIV/AIDS or by medications taken after an organ transplant.

**VALCYTE is used to treat CMV eye infections (known as CMV retinitis) in AIDS patients, which, if left untreated can cause blindness. It is not a cure for CMV eye infections.**

**VALCYTE is not effective against any underlying HIV infection.**

**VALCYTE is also used to prevent CMV infection in patients following organ transplantation.**

VALCYTE is not addictive.

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

Your doctor, however, may have prescribed VALCYTE for another purpose.

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

Animal and other laboratory studies have shown VALCYTE causes infertility, birth defects and cancer. It is possible that these effects may also occur in humans.

### Warnings

**Do not use VALCYTE if:**

- you are allergic to valganciclovir, ganciclovir, valaciclovir or aciclovir, or any of the ingredients listed at the end of this leaflet. 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
- Always check the ingredients to make sure you can use this medicine.
- You have very low blood counts for platelets (which help clotting), neutrophils (a type of white blood cell which defends against infection) or low haemoglobin (oxygen carrying substance in the blood).

### Use in children

There is limited information on the safety and effectiveness of the use of VALCYTE in children. Your doctor will advise you whether VALCYTE is suitable for your child.

**Check with your doctor if you:**

**you are allergic to any other medicines, foods, dyes or preservatives, especially any medicine which you have taken previously to treat your current condition.**

**you have any other health problems, especially the following:**

- you have a history of low blood counts for platelets (thrombocytopenia), neutrophils (neutropenia) or anaemia
- you have, or previously have had, poor kidney function

**you are pregnant or intend to become pregnant**

- VALCYTE is not recommended for use during pregnancy. VALCYTE may affect your developing baby if you take it during pregnancy. Your doctor will discuss the risks and benefits of using VALCYTE if you are pregnant.

**you are breast-feeding or intend to breast-feed**

- It is not known whether VALCYTE passes into breast milk. Breast-feeding is not recommended during therapy with VALCYTE

**you are a woman who could become pregnant and you are not using contraception**

- you must use a reliable form of contraception during VALCYTE therapy, and for at least 30 days after stopping VALCYTE, unless you are not sexually active.

**you are a sexually active man**

- you should use condoms during and for at least 90 days following treatment with VALCYTE unless it is certain that your female partner is not at risk of pregnancy.

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**

Make sure your doctor is aware that you are pregnant or plan to become pregnant or are breastfeeding or intend to breastfeed. You must use a reliable form of contraception during VALCYTE therapy, and for at least 30 days after stopping VALCYTE, unless you are not sexually active.

## **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 and VALCYTE may interfere with each other. These medicines include:**

- imipenem/cilastatin (Primaxin®) a combination of medicines used to treat some infections
- probenecid (e.g. Benemid®), a medicine used to treat gout
- zidovudine (AZT), Retrovir®, Combivir®, didanosine (ddI or Videx®), stavudine, other medicines used to treat HIV infection
- medicines for the treatment of cancer such as doxorubicin, vinblastine, vincristine, hydroxyurea
- mycophenolate mofetil (CellCept®), and other medicines used to prevent organ rejection after a transplant e.g. ciclosporin, tacrolimus.
- anti-infective agents such as trimpethroprim / sulphonamides, dapsone, pentamidine, flucytosine pegylated interferons plus ribavirin and amphotericin B

These medicines may be affected by VALCYTE, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist have more information on medicines to be careful with or avoid while taking VALCYTE.

**Ask your doctor or pharmacist if you are not sure about this list of medicines.**

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

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

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

### **How much to take**

Take VALCYTE exactly as your doctor has prescribed.

Your doctor will tell you how much VALCYTE solution to take each day.

### **Treatment of CMV Retinitis in AIDS (adult patients)**

- **Induction Treatment for adults (for active CMV retinitis)**

The usual dose is 900 mg twice daily with food for 21 days. Use the dispenser provided and take two 9 mL (450 mg) amounts of the solution in the morning and two 9 mL (450 mg) amounts in the evening.

- **Maintenance Treatment for adults (after induction treatment or for inactive CMV retinitis)**

The usual dose is 900 mg once daily with food. Use the dispenser provided and take two 9 mL (450mg) amounts of solution at the same time each day.

### **Prevention of CMV Disease in Transplantation for adults**

The usual dose is 900 mg once daily with food, starting within 10 days post transplantation until 100 days post transplantation.

If you have received a kidney transplant, the same daily dose is required until 200 days post transplantation.

Use the dispenser provided to take two 450mg amounts (i.e. 2 dispensers filled to the 9 mL graduation) of solution at the same time each day.

Your dose may have to be reduced or stopped if you have or develop low blood counts, have kidney disease, or if you are older than 65 years

### **Prevention of CMV Disease in Transplantation for children**

Your doctor will let you know the dose of VALCYTE suspension that you should give your child. Give the solution exactly as your doctor has prescribed.

### **How to take it**

VALCYTE solution will be made up from the powder with water by the pharmacist just before you receive it.

**Be careful when handling VALCYTE solution. You should avoid getting the solution on your skin or in your eyes. If you accidentally get the solution on your skin, wash the area thoroughly with soap and water. If you accidentally**

**get the solution in your eyes, rinse your eyes thoroughly with water.**

**It is important that you use the dispenser provided in the pack to measure your dose of VALCYTE solution.**

Two dispensers are provided, discard each dispenser after 20 applications. Each dispenser is designed to measure up to 10 mL (500 mg) of solution in 0.5 mL (25 mg) increments.

Always wash the dispenser thoroughly with distilled or boiled water and allow it to dry after you have taken your dose. Any remaining reconstituted solution should be discarded after 40 applications (20 applications per dispenser), or after 49 days, whichever occurs first. See Section 5 'Getting rid of any unwanted medicine' for instructions on how dispose of the medicine.

**Tell your doctor or pharmacist if you discard, lose or damage both dispensers.**

They will advise you on how to continue to take your medicine.

Once the solution has been prepared, follow the instructions below to withdraw and take your medicine.

1. Shake closed bottle well for about 5 seconds before each use.
2. Remove the child-resistant cap.
3. Before inserting the tip of the dispenser into bottle adapter, push the plunger completely down toward the tip of the dispenser. Insert tip firmly into opening of the bottle adapter.
4. Turn the entire unit (bottle and dispenser) upside down.
5. Pull the plunger out slowly until the desired amount of solution is withdrawn into the dispenser
6. Turn the entire unit right side up and remove the dispenser slowly from the bottle.
7. Dispense directly into mouth and swallow. Do not mix with any liquid prior to dispensing.
8. Close bottle with child-resistant cap after each use.
9. Immediately after administration disassemble the dispenser, rinse under running distilled or boiled water and air dry prior to next use.

Do not use the solution after the expiry date which is 49 days from the day of preparation.

#### **When to take VALCYTE**

- **Take VALCYTE solution during or immediately after a meal.**
- Take VALCYTE solution at about the same time each day for as long as the doctor tells you to.

#### **How long to take it**

- Continue taking VALCYTE until your doctor tells you to stop.

#### **If you forget to take VALCYTE**

VALCYTE should be used regularly at the same time each day.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember and then go back to taking it as you would normally.**

**Do not take a double dose to make up for the dose you missed.**

#### **If you use too much VALCYTE**

If you think that you have used too much VALCYTE, 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 VALCYTE?**

### **Things you should do**

Tell any other doctors, dentists and pharmacists who treat you that you are taking VALCYTE.

### **Call your doctor straight away if you become pregnant while taking VALCYTE**

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).

Condoms should be used by sexually active men while taking VALCYTE and for 90 days after stopping treatment.

Women who are of childbearing potential should use contraception during and for at least 30 days after stopping VALCYTE.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Keep all of your appointments with your doctor so that your progress can be checked.

### Things you should not do

Do not take VALCYTE to treat any other complaints unless your doctor tells you to.

Do not give VALCYTE to anyone else even if they have the same condition as you.

Do not stop taking VALCYTE or change the dosage without first checking with your doctor.

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

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

Be careful when handling the VALCYTE solution. Do not get the solution on your skin or in your eyes.

If you accidentally get the solution on your skin, wash the area thoroughly with soap and water. If you accidentally get the solution in your eyes, rinse your eyes thoroughly with water.

### Driving or using machines

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

VALCYTE may cause drowsiness, dizziness, confusion or seizures (fits) in some people and therefore may affect alertness. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

### Looking after your medicine

- Keep VALCYTE solution in the original bottle.
- Keep VALCYTE in the refrigerator (2-8°C). Do not freeze.

Follow the instructions in the carton 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.**

### When to discard your medicine

**Do not use VALCYTE solution after its expiry date (49 days after it has been made up) or after 40 applications (20 applications per dispenser), whichever occurs first.**

Your pharmacist will have written the expiry date on the bottle for you.

### 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.

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.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• diarrhoea</li><li>• vomiting</li><li>• nausea</li><li>• dizziness</li><li>• headache</li><li>• insomnia (inability to sleep)</li><li>• looking pale</li><li>• fever</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>• thinking, hearing or seeing things that are not real</li><li>• agitation</li><li>• fits</li><li>• confusion</li><li>• swelling of the tongue, lips or throat</li><li>• any sign of infection such as fever, chills, sore throat or mouth ulcers</li><li>• unexplained bruising or bleeding</li><li>• skin rash</li><li>• abdominal pain</li><li>• cough</li><li>• fatigue (tiredness)</li><li>• oral thrush (sore, creamy yellow raised patches in the mouth)</li><li>• worsening of your eyesight</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>

**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 VALCYTE contains

<b>Active ingredient (main ingredient)</b>	valganciclovir
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• povidone</li><li>• fumaric acid</li><li>• sodium benzoate (E211)</li><li>• saccharin sodium</li><li>• mannitol</li><li>• tutti-frutti flavour</li></ul>
<b>Potential allergens</b>	not applicable

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

### What VALCYTE looks like

VALCYTE powder is white to slightly yellow in colour and the reconstituted solution appears clear, colourless to brownish yellow in colour.

VALCYTE solution 50 mg/mL comes in a bottle with an adapter, and two oral dispensers. (Aust R 154382).

**The oral dispensers provided should not be used for measuring doses of any other medicines.**

VALCYTE is also available as 450mg film-coated tablets.

Not all dosage forms may be marketed.

### Who distributes VALCYTE

Pharmaco (Australia) Ltd

Level 9, Tower A

Zenith Towers

821 Pacific Highway

Chatswood NSW 2067

Australia

Phone: 1800 201 564

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