

# VALCYTE<sup>®</sup> Powder for Oral Solution



Pronounced VAL-SITE

contains the active ingredient valganciclovir

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about VALCYTE Powder for Oral Solution.

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 VALCYTE 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 VALCYTE is used for

VALCYTE contains the active ingredient valganciclovir. In the body valganciclovir rapidly changes to ganciclovir.

VALCYTE belongs to a class 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.

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

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

VALCYTE is not addictive.

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

### Before you take 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.

#### **When you must not take it**

**Do not take VALCYTE if**

- 1. you have had an allergic reaction to VALCYTE,**

**ganciclovir, valaciclovir or aciclovir or any 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

- 2. 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)**
- 3. the package is torn or shows signs of tampering**
- 4. 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.

**If you are not sure if you should be taking VALCYTE, talk to your doctor.**

#### **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.

#### **Before you start to take it**

**Tell your doctor if**

- 1. you are allergic to any other medicines, foods, dyes or preservatives.**

Especially any medicine which you have taken previously to treat your current condition

**2. 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

**3. 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.

**4. 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.

**If you have not told your doctor about any of the above, tell them before you start taking VALCYTE.**

**Taking other medicines**

**Tell your doctor if you are taking any other medicines, including any that you have bought without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may interfere with VALCYTE. These medicines include:

- probenecid, a medicine used to treat gout
- zidovudine (AZT) a medicine used to treat HIV infection

- didanosine (ddI), a medicine used to treat HIV infection
- imipenem/cilastatin, a combination of medicines used to treat some infections
- mycophenolate mofetil, a medicine used to prevent organ rejection after a transplant
- medicines for the treatment of cancer such as vincristine, adriamycin, hydroxyurea
- anti-infective agents such as dapsone, pentamidine, flucytosine and amphotericin B
- other medicines for the treatment of HIV or HIV-related infections such as nucleoside analogues (lamivudine, also known as 3TC; stavudine, also known as D4T; zalcitabine also known as ddC; abacavir; lamivudine / zidovudine or; abacavir / lamivudine / zidovudine combinations).

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 will advise you.

Your doctor or pharmacist has 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.**

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**How to take VALCYTE**

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

They may differ from the information contained in this leaflet.

**How much to take**

**Take VALCYTE Powder for Oral Solution exactly as your doctor has prescribed.**

Your doctor will tell you how much VALCYTE Powder for Oral Solution to take.

**Treatment of CMV Retinitis in AIDS**

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

The usual dose is 900 mg twice daily with food for 21 days

Use the dispenser provided and take two 450 mg amounts (i.e. 2 dispensers filled to 450 mg graduation) of the solution in the morning and two 450 mg amounts in the evening.

- **Maintenance Treatment (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 450 mg amounts of solution (i.e. 2 dispensers filled to 450 mg graduation) at the same time each day.

**Prevention of CMV Disease in Transplantation**

The usual dose is 900 mg once daily with food, starting within 10 days of your organ transplant until 100 days after the transplant.

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

Use the dispenser provided to take two 450 mg amounts (i.e. 2 dispensers filled to 450 mg 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.

### **How to take it**

VALCYTE Powder for Oral Solution will be made up by the pharmacist just before you receive it.

You have to 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 in case one of them gets lost or damaged. Each dispenser is designed to measure up to a 500 mg amount of solution in 25 mg increments.

Always wash the dispenser thoroughly and allow it to dry after you have taken your dose.

**Tell your doctor or pharmacist if you 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 medication.

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 tap 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 it**

**Take VALCYTE Powder for Oral Solution during or immediately after a meal.**

If you take VALCYTE Powder for Oral Solution on an empty stomach, it may not work as well.

**Take VALCYTE Powder for Oral Solution at about the same time each day.**

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take VALCYTE Powder for Oral Solution.

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

**Continue taking VALCYTE Powder for Oral Solution until your doctor tells you to stop.**

### **If you forget to take it**

**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 are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering your dose, ask your pharmacist for some hints.**

### **If you take too much (overdose)**

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

You may need urgent medical attention.

**Keep telephone numbers for these places handy.**

**If you are not sure what to do, contact your doctor or pharmacist.**

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## **While you are taking VALCYTE**

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### **Things you must do**

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

A barrier contraceptive should be used while taking VALCYTE and for 90 days after stopping treatment.

Tell your doctor 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).

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.

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

### ***Things you must not do***

Do not stop taking VALCYTE or change the dose 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.

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

### ***Things to be careful of***

Be careful when handling the VALCYTE Powder for Oral 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.

Be careful driving or operating machinery until you know how VALCYTE affects you.

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

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### **Side effects**

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

VALCYTE helps most people with CMV infections but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- dizziness
- looking pale
- diarrhoea
- nausea
- fever
- vomiting
- headache

These are more common side effects of VALCYTE and are usually short-lived.

Tell your doctor if you immediately if you notice any of the following:

- skin rash
- abdominal pain
- cough
- fatigue (tiredness)
- oral thrush (sore, creamy yellow raised patches in the mouth)
- insomnia (inability to sleep)
- worsening of your eyesight

These side effects may be serious. You may require medical attention.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- swelling of the tongue, lips or throat
- any sign of infection such as fever, chills, sore throat or mouth ulcers
- unexplained bruising or bleeding
- thinking, hearing or seeing things that are not real
- confusion
- agitation
- fits

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

**Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.**

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

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## After taking VALCYTE

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### **Storage**

**Keep VALCYTE Powder for Oral Solution in the original bottle.**

**Keep VALCYTE in the refrigerator (2 – 8 °C). Do not freeze.**

If you do not keep VALCYTE in the refrigerator, it may not work as well.

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

### **Disposal**

**Do not use VALCYTE Powder for Oral Solution after its expiry date (49 days after it has been made up).**

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

**If your doctor tells you to stop taking VALCYTE, or the solution has passed its expiry date, ask your pharmacist what to do with any solution that is left over.**

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## Product description

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### **Availability**

VALCYTE Powder for Oral Solution 50 mg/mL comes in a

bottle with an adapter, and two oral dispensers.

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

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

### **What VALCYTE looks like**

VALCYTE Powder for Oral Solution is a solution that is white to slightly yellow in colour.

### **Ingredients**

**Active ingredient** - valganciclovir

- each one mL of VALCYTE oral solution contains 50 mg valganciclovir

**Inactive ingredients** –

VALCYTE Powder for Oral Solution also contains:

- povidone K-30
- fumaric acid
- sodium benzoate (E211)
- saccharin sodium
- mannitol
- tutti-frutti flavour

### **Distributor**

VALCYTE is distributed by:

Roche Products Pty Limited  
ABN 70 000 132 865  
4-10 Inman Road  
Dee Why NSW 2099  
AUSTRALIA

Customer enquiries: 1800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

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