

VALCYTE®

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 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.

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

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

Do not take VALCYTE if 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)

Do not take VALCYTE after the expiry date (EXP) printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure if you should start 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

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.

If you have not told your doctor about any of the above, tell him/her before you start taking VALCYTE.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a

prescription from a 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, also known as D4T, 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 trimethoprim / 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.

How to take 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 solution exactly as your doctor has prescribed.

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

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.

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 10 mL (500 mg) of solution in 0.5 mL (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 solution during or immediately after a meal.

If you take VALCYTE solution on an empty stomach, it may not work as well.

Take VALCYTE 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 solution.

How long to take it

Continue taking VALCYTE 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.

While you are using VALCYTE

Things you must do

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

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).

If you become pregnant while taking VALCYTE, tell your doctor immediately.

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 must 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.

Things to be careful of

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.

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. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

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.

If you are over 65 years of age you may have an increased chance of getting side effects.

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 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

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

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.

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

After using VALCYTE

Storage

Keep VALCYTE 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 children cannot reach it.

Disposal

Do not use VALCYTE 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.

Product description

Availability

VALCYTE 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 450mg film-coated tablets.

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.

Ingredients

Active ingredient - valganciclovir

- each one mL of VALCYTE solution contains 50 mg valganciclovir

Inactive ingredients -

VALCYTE solution also contains:

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

Manufacturer

VALCYTE is distributed by:

Roche Products Pty Limited

ABN 70 000 132 865

Level 8, 30-34 Hickson Road

Sydney NSW 2000

AUSTRALIA

Medical enquiries: 1800 233 950

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

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