

Consumer Medicine Information

VALCYTE[®]

Valganciclovir
450 mg tablets

What is in this leaflet

This leaflet answers some common questions about Valcyte tablets.

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 expected 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.

After taking Valcyte tablets, valganciclovir is quickly changed in your body to release ganciclovir, which is the active medicine. 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 the 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 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, or ganciclovir or any ingredients listed at the end of this leaflet.**

Some 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 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 medicines like aciclovir , valaciclovir, famciclovir or penciclovir.**

These medicines are from the same class as Valcyte and allergic reactions may occur.

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

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

- 3. 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
- if you have poor liver function

- 4. you are pregnant or plan 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.

5. 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 treatment with Valcyte.

6. 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.

7. you are a sexually active man

You should use condoms while you are taking Valcyte and for a further 90 days after you have stopped taking it. Valcyte may affect the production of sperm. Your doctor will discuss the risks and benefits of using Valcyte.

If you have not told your doctor about any of the above, do so before you start taking Valcyte.

Taking other medicines

Tell your doctor or pharmacist 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 treatment for gout
- zidovudine, didanosine, stavudine, also known as D4T, – medicines used for people with HIV infection
- imipenem-cilastatin – a combination antibiotic medicine
- medicines used to prevent rejection after a transplants such as mycophenolate mofetil, ciclosporin, tacrolimus
- medicines used for the treatment of cancer such as vincristine, vinblastine, doxorubicin, hydroxyurea
- anti-infective agents such as trimethoprim.sulfonamides, dapsone, pentamidine, flucytosine, pegylated interferons 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 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.

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.

How much to take

Take Valcyte exactly as your doctor has prescribed.

Your doctor will tell you how many Valcyte tablets to take each day.

Treatment of CMV Retinitis in AIDS

The usual starting dose (initial treatment) is two 450 mg tablets twice a day with food (a total of 4 tablets per day) for 21 days.

The usual maintenance dose or dose for people with inactive CMV retinitis is two 450 mg tablets once a day with food.

Prevention of CMV Disease in Transplantation

The usual dose is 900 mg (two 450 mg tablets) once daily with food, starting within 10 days of your organ transplant and continuing until 100 days after the transplant.

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

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

Swallow tablets whole with a glass of water. Valcyte must be taken with food. If you are unable to eat for any reason, you should still take the tablets when they are due.

When to take it

Take Valcyte during or immediately after a meal.

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

Take your Valcyte 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 to remember when to take Valcyte.

How long to take it

Continue taking Valcyte 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 National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to your nearest Accident and Emergency centre 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 taking Valcyte

Things you must do

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

Tell your doctor if either you or your partner becomes pregnant while taking Valcyte.

It is extremely important that both men and women of child-bearing age use effective contraception during treatment with Valcyte.

If you need advice on contraception ask your doctor before you start taking Valcyte.

Men should use condoms while taking Valcyte and should continue to use condoms for 90 days after treatment has finished.

Women should use effective contraception during and for 30 days after treatment has finished.

See your doctor regularly so that your CMV disease, blood cell counts and any other potential side effects may be monitored carefully.

If blood cells counts are low then this may reduce your ability to fight infection, or for your blood to clot efficiently. If left undetected these effects may contribute to death or serious illness.

If you have a CMV eye infection you must see your doctor regularly to monitor the condition of your retina (part of your 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.

Tell your doctor if you feel the tablets are not helping your condition.

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.

Be careful when handling Valcyte tablets. Do not break or crush them. If you accidentally touch broken or crushed tablets, wash your hands thoroughly with soap and water. If any powder from the tablet gets in your eyes, rinse your eyes thoroughly with water.

Things to be careful of

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

Valcyte may cause, 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, operate machinery or do anything else that could be dangerous if you are drowsy or dizzy or not alert.

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 some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the 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:

- looking pale and/or dizziness (anaemia)
- diarrhoea or constipation
- feeling sick (nausea) or vomiting
- fever
- headache
- indigestion
- tingling or numbness of the hands and feet
- shaking or tremors
- runny nose, sore throat or nasal passages
- difficulty in breathing
- loss of appetite, weight loss
- painful, swollen joints, muscle pain
- pain when passing urine

These are the more common side effects of Valcyte.

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

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

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

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

- symptoms of an allergic reaction: 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
- any signs of infection – fever, chills, sore throat or mouth ulcers.
- any unexplained bruising or bleeding
- abnormal thoughts, confusion, agitation, hallucinations (seeing, hearing or feeling things that are not there)
- convulsions (fits)
- problems with your eyesight such as seeing bright flashes of light

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 on this list.

After taking Valcyte

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well or may get damaged.

Keep Valcyte in a cool dry place where the temperature stays below 30 °C.

Do not store it or any other medicine in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Valcyte where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Valcyte, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

Availability

Valcyte comes in one tablet strength, 450 mg.

Valcyte comes in bottles containing 60 tablets.

What Valcyte looks like

Valcyte 450mg tablets are pink convex oval tablets with "VGC" on one side and "450" on the other.

Ingredients

Active ingredient – valganciclovir 450 mg

Inactive ingredients – povidone K-30, crospovidone, microcrystalline cellulose (460), stearic acid (570), hydroxypropyl methylcellulose, titanium dioxide (171), polyethylene glycol, red iron oxide (172), polysorbate 80 (433).

Valcyte tablets are lactose and gluten free.

Distributor

Valcyte is distributed by:

Roche Products (New Zealand) Limited P O Box 109113 Newmarket Auckland 1149 NEW ZEALAND

Medical enquiries: 0800 656 464

This leaflet was prepared on 29 November 2017.