

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, the valganciclovir is quickly changed in your body to release ganciclovir, which is the active medicine. Ganciclovir prevents the growth and the increase in numbers of a virus called cytomegalovirus (CMV).

Many people have been infected with CMV. This usually happens before reaching adulthood but a few people are first infected when in adulthood. There may be no symptoms at the time of infection but some people do have a mild flu-like illness for a while. After infection the virus remains in the body, but it does not usually cause any further symptoms in healthy people.

In people whose immune system is not working properly, there may be an increase in the numbers of CMV that are already in the body. If this happens, or if people catch CMV for the first time when their immunity to infections is poor, the virus can spread to all parts of the body and cause many different signs and symptoms of illness.

When this happens, one of the places that CMV can attack is the back of the eye (the retina), where it causes inflammation. This is called CMV retinitis. If CMV retinitis is not treated, it can cause permanent damage to the eyes. The result can be poor vision or even blindness.

VALCYTE can be used for the initial treatment of CMV retinitis in patients whose immune system is weakened by acquired immunodeficiency syndrome (AIDS). VALCYTE can also be used as a maintenance treatment to try and stop further attacks of inflammation in the retina.

VALCYTE is not effective against any underlying HIV infection.

VALCYTE can also be used for the prevention of CMV disease in solid organ transplant patients at risk.

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.

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

Before you take VALCYTE

When you must not take it

Do not take VALCYTE if:

- 1. you have had an allergic reaction to VALCYTE, or ganciclovir (e.g. Cymevene[®]), or any ingredients listed at the end of this leaflet**
- 2. you have had an allergic reaction to aciclovir (e.g. Acicvir[®], Acyclovir[®], Lovir[®], Zovirax[®]) or valaciclovir**
You may be more likely to have an allergic reaction to VALCYTE.
- 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.

Use in children

Safety and effectiveness in children have not been established. The use of VALCYTE in children is not recommended.

Before you start to take it

Tell your doctor if:

- 1. you are pregnant or plan to become pregnant**
VALCYTE is not generally recommended for use in pregnant women unless the benefits of treatment outweigh the risks to the unborn baby.
- 2. you are a male who has a female partner of child-bearing age**
You should use condoms while you are taking VALCYTE and for a further 90 days after you have stopped taking it.
- 3. you are breast-feeding or plan to breast-feed**
It is not known whether VALCYTE passes into breast milk. Your doctor will discuss the risks and benefits of using VALCYTE if you are breast-feeding.
- 4. you have any other health problems, especially the following:**
 - if your blood counts (numbers of red and white blood cells, and platelets) are low
 - you have kidney disease
 - you are on haemodialysis
- 5. you are allergic to any other medicines, foods, dyes or preservatives**

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 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:

- imipenem-cilastatin (e.g. Primaxin[®]) – a combination antibiotic medicine
- probenecid – a treatment for gout
- zidovudine (e.g. Combivir[®], Retrovir[®]), didanosine (e.g. Videx[®]) – medicines used for people with HIV infection
- mycophenolate mofetil (e.g. CellCept[®]), cyclosporin (e.g. Neoral[®], Sandimmun[®]) – medicines used for people that have had organ transplants
- dapsone, pentamidine (e.g. Pentacarinat[®]) – anti-infective medicines
- flucytosine (e.g. Ancotil[®]), amphotericin B (e.g. AmBisome[®], Fungilin[®], Fungizone[®]) – antifungal medicines
- vincristine, vinblastine, doxorubicin (e.g. Adriamycin[®], Caelyx[®]), hydroxyurea (e.g. Hydrea[®]) – anti-cancer medicines
- some medicines used to treat HIV, hepatitis or other viral infections

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.

It is very important that you do not take more than the number of VALCYTE tablets prescribed for you by your doctor because an overdose of VALCYTE could have life-threatening side effects.

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. Each day's tablets may be divided evenly into two (morning and evening) daily doses.

The usual maintenance dose or dose for people with inactive CMV retinitis is two 450 mg tablets once a day with food. If the retinitis worsens, initial treatment may be repeated.

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 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.

If your kidneys are not working properly, your doctor may instruct you to take fewer tablets each day or may ask you to take VALCYTE only on some days of the week. It is VERY IMPORTANT that you follow these special dose instructions from your doctor.

How to take it

Swallow tablets whole with some water or other liquid. VALCYTE should be taken with food. If you are unable to eat for any reason, you should still take the tablets when they are due, but your blood levels of the active medicine will be lower.

Your doctor may decide to add an additional tablet (L-thyroxine), to help control your condition.

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 the tablets.

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.

In case of an 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.

Taking more than the recommended dose can cause serious side effects, particularly affecting your blood or kidneys. Also, the risk of any of the other side effects mentioned in this leaflet may be greater.

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 become 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.

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.

Your doctor may ask you to have regular blood tests to help determine how you are responding to treatment.

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 give VALCYTE to anyone else even if they have the same condition as you.

Do not use VALCYTE to treat other complaints unless your doctor says to.

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

VALCYTE may cause dizziness, drowsiness, confusion, convulsions and/or a lack of co-ordination in some people. 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 experience any of these effects. If you drink alcohol, dizziness and drowsiness may be worse.

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 retinitis, 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.

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:

- diarrhoea
- sore, creamy-yellow raised patches in your mouth (oral thrush)
- headache
- fever
- tiredness (fatigue)
- feeling sick (nausea)
- vomiting
- abdominal pain
- indigestion
- skin rash (dermatitis), itchy skin, acne
- looking pale and/or dizziness (anaemia)
- tingling or numbness of the hands and feet
- shaking or tremors
- unable to sleep (insomnia)
- cough
- runny nose, sore throat or nasal passages
- blurred vision
- feeling sad or depressed
- 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 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
- pneumonia: a serious lung infection with fever, chills, shortness of breath, cough, phlegm and occasionally blood.
- any unexplained bleeding
- convulsions (fits)
- abnormal thoughts, confusion, agitation, hallucinations (seeing, hearing or feeling things that are not there)
- any signs of infection – fever, chills, inflammation (pain, swelling, redness and heat)
- problems with your eyesight such as seeing bright flashes of light

These may be serious side effects. You may need urgent medical attention.

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.

VALCYTE tablets should be handled with care and should not be broken or crushed.

If you do accidentally touch damaged tablets, wash your hands thoroughly with soap and water. If any powder from the tablets gets in your eyes, rinse your eyes thoroughly with sterile or plain water.

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.

What VALCYTE looks like

Pink convex oval tablets with "VGC" on one side and "450" on the other.

Ingredients

Active ingredient – valganciclovir, 450 mg

Inactive ingredients – povidone, crospovidone, microcrystalline cellulose, stearic acid, hydroxypropyl methylcellulose, titanium dioxide, polyethylene glycol, red iron oxide, polysorbate.

VALCYTE tablets are lactose and gluten free.

Distributor

VALCYTE is distributed by:

Roche Products (New Zealand) Limited
P O Box 12492 Penrose
Auckland 1642
NEW ZEALAND



Customer enquiries: 0800 656 464

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