

VALCYTE(R) Tablets

Pronounced VAL-SITE

contains the active ingredient valganciclovir

Consumer Medicine Information

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 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.

VALCYTE belongs to a class of medicines used to treat viral infections.

Once swallowed, the body rapidly changes VALCYTE to ganciclovir (CYMEVENE(R)) which works by stopping certain viruses from growing in the body.

VALCYTE acts against cytomegalovirus or CMV (a type of herpes virus). CMV causes infections mainly in people with poor immunity. Poor immunity can

be caused by HIV/AIDS or transplant medications.

VALCYTE helps control CMV eye infections (known as CMV retinitis) in AIDS patients which if left untreated can cause blindness. Unfortunately it is not a cure for CMV eye infections.

VALCYTE is not effective against any underlying HIV- infection.

VALCYTE tablets may also be used to prevent CMV infection and disease in patients following 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 has caused 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 (CYMEVENE), or**

a drug from the same family called aciclovir (Zovirax(R), Acyclovir-V(R) or Zyclir(R)) or any ingredients listed at the end of this leaflet

- 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**
- 3. you are pregnant**
your baby may absorb this medicine in the womb and therefore there is a possibility of harm to the baby
- 4. you are breast-feeding or intend to breast-feed**
It is likely that VALCYTE passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected
- 5. the package is torn or shows signs of tampering**
- 6. 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

The effects of VALCYTE tablets in children is not known. Therefore their use in children is not recommended.

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 haemoglobin (anaemia).
 - you have or previously have had poor kidney function

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 from a pharmacy, supermarket or health food shop.

Some medicines may interfere with VALCYTE. These medicines include:

- * probenecid (Benemid(R))
- * zidovudine (AZT or Retrovir(R))
- * didanosine (ddI or Videx(R))
- * imipenem/cilastatin (Primaxin(R))
- * mycophenolate mofetil (Cellcept(R))
- * 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 or 3TC/Zeffix(R); stavudine/D4T or Zerit(R); zalcitabine/ddc or Hivid(R); abacavir or Ziagen(R);

lamivudine/zidovudine or Combivir(R); and abacavir/lamivudine/ zidovudine or Trizivir(R)).

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.

You must not switch between CYMEVENE capsules and VALCYTE tablets as the dosage for each is different. There is a risk of overdosage if too much of either medication is taken.

Consult your doctor or pharmacist if you are unsure of your correct dosage.

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

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

The usual dose is 900mg (two 450mg tablets) twice daily with food for 21 days

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

The usual dose is 900mg (two 450mg tablets) once daily with food.

Prevention of CMV Disease in Transplantation.

The usual dose is 900mg (two 450mg tablets) once daily with food, starting within 10 days of transplantation until 100 days after/following transplant.

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

How to take it

Swallow tablets whole with a glass of water. VALCYTE must be taken with food.

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.

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 Poisons Information Center (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.

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 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 there is a possibility of your partner becoming pregnant, a barrier contraceptive should be used while taking VALCYTE and for 90 days after stopping.

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.

You must not try to break or crush the tablets.

If you do so accidentally, thoroughly wash your hands with soap and water.

Things to be careful of

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.

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.

Unwanted effects may be due to VALCYTE, or other medications, or any disease or condition you may also have. You should notify your doctor if these or any other effects occur.

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.

Many unwanted effects commonly reported in people with HIV appear to be related to their medical condition. The following list are unwanted effects seen in people taking VALCYTE which may or may not be caused by their medication:

More common

- * low white blood cell count
- * anaemia
- * diarrhoea
- * nausea
- * fever

Less common

- * vomiting
- * rash
- * abdominal pain
- * headache
- * cough
- * fatigue (tiredness)
- * oral thrush (sore, creamy yellow raised patches in the mouth)
- * insomnia (inability to sleep)

Rare or very rare, but may be serious. You may need urgent medical attention

- * severe allergic reactions
- * low red and white blood cell counts
- * bleeding
- * infections of the body or blood
- * seizures (fits)
- * mental conditions such as hallucinations, confusion, agitation, psychosis.

If you notice any of the following you should see your doctor immediately

- * a deterioration or worsening of your eye sight even if you are taking VALCYTE
- * bruising or purple spots
- * any sign of infection such as fever, chills, sore throat or mouth ulcers
- * tiredness
- * skin rash.

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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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.

Keep VALCYTE in a cool dry place where the temperature stays below 30 degrees 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 450 mg film coated tablets

VALCYTE comes in bottles containing 60 tablets.

What VALCYTE looks like

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

Ingredients

Active ingredient - valganciclovir

- * each VALCYTE tablet contains 450mg of valganciclovir

Inactive ingredients -

VALCYTE film coated tablets also contain

- * microcrystalline cellulose (460)
- * povidone K-30
- * crospovidone
- * stearic acid (570)
- * hypromellose
- * titanium dioxide (171)
- * macrogol 400
- * polysorbate 80 (433)
- * red iron oxide (172)

VALCYTE capsules are lactose and gluten free.

Distributor

VALCYTE is distributed by:
Roche Products Pty Limited
ACN 000 132 865
ABN 70 000 132 865
4-10 Inman Road
Dee Why NSW 2099

Customer enquiries: 1 800 233 950

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

Australian Registration Number
AUST R 82903

This leaflet was prepared in
December 2004.