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1. What Valcyte is used for

Valcyte contains the active ingredient *valganciclovir hydrochloride*.

Valcyte is used to treat cytomegalovirus (CMV) retinitis (an eye infection caused by a type of herpes virus) in acquired immunodeficiency syndrome (AIDS) patients as it can cause blindness if untreated.

Valcyte is also used to prevent CMV disease in patients who are not infected with CMV but received organ transplantation from a CMV infected donor.

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

Valcyte is not addictive

Valcyte is available only with a doctor's prescription

2. How Valcyte works

Valcyte contains the active ingredient *valganciclovir hydrochloride*.

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.

3. Before you use Valcyte

When you must not use it

Do not use Valcyte if:

1. **You are allergic to:**
 - **Valcyte, acyclovir, ganciclovir, valaciclovir or any of the ingredients listed at the end of this leaflet.**Some of the symptoms of an allergic reaction may include:
 - **shortness of breath**
 - **wheezing or difficulty in breathing**
 - **swelling of the face, lips, tongue or other parts of the body**
 - **rashes, itching, hives on the skin**
2. **You have very low blood counts for platelets (used for clotting), neutrophils (a type of white blood cell used as defence against infections), haemoglobin (an oxygen carrying substance in the blood)**

3. The packaging is torn or shows signs of tampering

The expiry date (EXP) printed on the pack has passed. If you use this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should start taking Valcyte, contact your doctor.

Your doctor will advise you whether Valcyte is suitable to be used in your child as there is limited information on the effectiveness and safety of the use of Valcyte in children.

Before you start to use it

You must tell your doctor if:

1. **You are pregnant or plan to become pregnant**

Valcyte is not recommended to be used during pregnancy as it may cause harm to your developing baby if taken during pregnancy.
2. **You are breastfeeding or plan to breastfeed**

It is not known whether Valcyte passes into the breast milk.

Valcyte is not recommended for use if you are breastfeeding. Your doctor will assess the risks and benefits of you taking Valcyte if you are breastfeeding.

3. **You have any other health problems, particularly:**
 - you have low blood counts for platelets (thrombocytopenia), neutrophils (neutropenia) and haemoglobin (anemia).
4. **You have any allergies to any other medicines, foods, preservatives or dyes**

If you have not told your doctor or pharmacist about any of the above, tell them 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 may interfere with Valcyte. These include:

- probenecid, a medicine used to treat gout
- zidovudine and didanosine, medicines used to treat HIV infections
- 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 hydroxyurea, vincristine, adriamycin
- anti-infective agents such as dapsone, flucytosine, pentamidine, amphotericin B
- other medicines for the treatment of HIV or HIV-related infections, such as nucleoside analogues (lamivudine, stavudine, zalcitabine, 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 take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and 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.

4. How to use Valcyte

How much to use

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

Take Valcyte exactly as your doctor has prescribed.

Treatment of CMV Retinitis in AIDS patients.

- **Induction treatment for active CMV patients**
The normal dose is 900mg (two 450mg tablets) twice daily with food for 21 days.
- **Maintenance treatment (after induction treatment or for inactive CMV patients)**
The normal dose is 900mg (two 450mg tablets) once daily with food.
- **Prevention of CMV disease in transplantation**
The normal dose is 900mg (two 450mg tablets) once daily with food, starting within 10 days of your organ transplant until 100 days after the organ transplant.

If you have had a kidney transplant, the normal dose is 900mg (two 450mg tablets) once daily with food, starting within 10 days of your organ transplant until 200 days after the organ transplant.

Your dose may have to be reduced or stopped if you have or develop low

blood counts, if you have kidney disease or if you are over 65 years of age.

Take Valcyte exactly as your doctor has prescribed.

How to use Valcyte

Tablets should be swallowed whole with a glass of water and taken with food.

Do not chew the tablets.

When to use it

Valcyte should be taken during or immediately after a meal.

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

Valcyte should be taken at the same time every day.

This will give you the best effect and will help you remember when to take the tablets every day.

If you are not sure when to take Valcyte, ask your doctor.

How long to use it

Continue taking your Valcyte tablets until your doctor tells you to stop.

If you forget to use it

Do not try to make up for missed doses by taking an extra dose. If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

If you have missed several doses, please inform your doctor and follow the advice given to you.

If you use too much (overdose)

You may need urgent medical attention. Contact your doctor or visit the nearest Accident & Emergency Department immediately (bring along the medication, carton and this leaflet if possible). Do this

even if there are no signs of discomfort or poisoning.

5. While you are using it

Things you must do

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

You must use a barrier contraceptive while taking Valcyte and for 90 days after stopping treatment.

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

Valcyte can cause birth defects (serious harm to unborn babies).

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 CMV disease, blood cell counts or any other potential side effects may be monitored regularly.

Low blood cell counts may reduce your ability to fight infections or for your blood to clot effectively. If left undetected, it may lead to the development of serious illness or death.

If you have a CMV eye infection, you should also see your doctor regularly to monitor the condition of your retina (part of our eye).

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 their symptoms seem similar to yours or they have the

same condition as you.

Do not take any other medicines whether they require prescriptions or not without first consulting with your doctor or a pharmacist.

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

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 may therefore affect alertness.

6. Side effects

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. 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:

- diarrhoea
- vomiting
- nausea (feeling like you want to vomit)
- fever or increased temperature sensitivity
- dizziness or headache

- looking pale

These are the more common side effects of Valcyte. Your doctor may advise to change the dose of Valcyte that you are taking if you experience any of the above side effects.

Tell your doctor immediately if you experience any of the following side effects:

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

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

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

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

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website

npra.gov.my [Consumers-> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. Storage and Disposal of Valcyte

Storage

Keep out of reach and sight of children.

Do not store above 30 °C

Store the medicine in its bottle until you need to take it.

Tablets should not be broken or crushed. Avoid direct contact of broken or crushed tablets with skin or mucous membrane. If such contact occurs, wash thoroughly with soap and water; rinse your eyes thoroughly with water.

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.

Medicine should not be disposed of via wastewater and disposal through household waste should be avoided.

8. Product Description

What it looks like

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

Ingredients

Active ingredient – valganciclovir

Each tablet of Valcyte contains 450mg of valganciclovir

Inactive ingredients -

The tablets also contain:

- povidone
- crospovidone
- stearic acid powder
- microcrystalline cellulose

The tablets are coated with a film-coating which contains:

- hydroxypropyl methylcellulose
- titanium dioxide (E171)
- polysorbate

VALCYTE®

Valganciclovir hydrochloride (450mg)

Consumer Medication Information Leaflet (RiMUP)

- polyethylene glycol
- red iron oxide (E172)

MAL number:

Valcyte tablets 450mg
(MAL20040021ACRZ)

9. Manufacturer

Made for CHEPLAPHARM
Arzneimittel GmbH,
Greifswald, Germany
by Patheon Inc, Mississauga,
Canada.

Product Registration Holder

DKSH Malaysia Sdn. Bhd.
B-11-01, The Ascent, Paradigm,
No. 1, Jalan SS7/26A, Kelana Jaya,
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Malaysia

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