

Package leaflet: Information for the user

Valcyte 50 mg/ml powder for oral solution valganciclovir

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Valcyte is and what it is used for
2. What you need to know before you take Valcyte
3. How to take Valcyte
4. Possible side effects
5. How to store Valcyte
6. Contents of the pack and other information

1. What Valcyte is and what it is used for

Valcyte belongs to a group of medicines, which work directly to prevent the growth of viruses. In the body the active ingredient in the powder, valganciclovir, is changed into ganciclovir. Ganciclovir prevents a virus called cytomegalovirus (CMV) from multiplying and invading healthy cells. In patients with a weakened immune system, CMV can cause an infection in the body's organs. This can be life threatening.

Valcyte is used:

- for the treatment of CMV-infections of the retina of the eye in adult patients with acquired immunodeficiency syndrome (AIDS). CMV-infection of the retina of the eye can cause vision problems and even blindness.
- to prevent CMV-infections in adults and children who are not infected with CMV and who have received an organ transplant from somebody who was infected by CMV.

2. What you need to know before you take Valcyte

Do not take Valcyte

- if you are allergic to valganciclovir, ganciclovir or any of the other ingredients of this medicine (listed in section 6).
- if you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Valcyte:

- if you are allergic to aciclovir, penciclovir, valaciclovir or famciclovir. These are other medicines used for viral infections.

Take special care with Valcyte

- if you have low numbers of white blood cells, red blood cells or platelets (small cells involved in blood clotting) in your blood. Your doctor will carry out blood tests before you start taking Valcyte and more tests will be done while you are taking the medication.
- if you are having radiotherapy.
- if you have a problem with your kidneys. Your doctor may need to prescribe a reduced dose for you and may need to check your blood frequently during treatment.

Other medicines and Valcyte

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription.

If you take other medicines at the same time as taking Valcyte the combination could affect the amount of drug that gets into your blood stream or could cause harmful effects. Tell your doctor if you are already taking medicines that contain any of the following:

- imipenem-cilastatin (an antibiotic). Taking this with Valcyte can cause convulsions (fits)
- zidovudine, didanosine, lamivudine, stavudine, tenofovir, abacavir, emtricitabine or similar kinds of drugs used to treat AIDS
- adefovir or any other medicines used to treat Hepatitis B
- probenecid (a medicine against gout). Taking probenecid and Valcyte at the same time could increase the amount of ganciclovir in your blood
- mycophenolate mofetil, ciclosporin or tacrolimus (used after transplantations)
- vincristine, vinblastine, doxorubicin, hydroxyurea or similar kinds of drugs to treat cancer
- trimethoprim, trimethoprim/sulpha combinations and dapsone (an antibiotic)
- pentamidine (drug to treat parasite or lung infections)
- flucytosine or amphotericin B (anti-fungal agents)

Valcyte with food and drink

Valcyte should be taken with food. If you are unable to eat for any reason, you should still take your dose of Valcyte as usual.

Pregnancy, breast-feeding and fertility

You should not take Valcyte if you are pregnant unless your doctor recommends it. If you are pregnant or planning to become pregnant you must tell your doctor. Taking Valcyte when you are pregnant could harm your unborn baby.

You must not take Valcyte if you are breast-feeding. If your doctor wants you to begin treatment with Valcyte you must stop breast-feeding before you start taking your medication.

Women of childbearing age must use effective contraception when taking Valcyte and for at least 30 days after treatment has finished.

Men whose partners could become pregnant should use condoms while taking Valcyte and should continue to use condoms for 90 days after treatment has finished.

Driving and using machines

Do not drive or use any tools or machines if you feel dizzy, tired, shaky or confused while taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

Valcyte contains sodium benzoate and sodium (salt)

This medicine contains 100mg of sodium benzoate in each 12g bottle, which is equivalent to 1mg/ml after reconstitution. Benzoate salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

For patients on a sodium-controlled diet, this medicine contains a total of 0.188 mg/ml sodium, that is to say essentially 'sodium-free'.

3. How to take Valcyte

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You have to be careful when handling the 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 any solution in your eyes, rinse your eyes thoroughly with water.

You must stick to the daily dose of the oral solution as instructed by your doctor to avoid overdose.

Valcyte oral solution should, whenever possible, be taken with food – see section 2.

It is important that you use the dispenser provided in the pack to measure your dose of Valcyte solution. Do not use these dispensers for another product. Two dispensers are provided in case one of them gets lost or damaged. Each dispenser is designed to measure up to a 10 ml (500 mg) amount of solution in 0.5 ml (25 mg) increments. 1 ml Valcyte oral solution corresponds to 50 mg valganciclovir.

Always wash the dispenser thoroughly and allow it to dry after you have taken your dose.

Contact your doctor or pharmacist if both dispensers are lost or damaged, and they will advise you on how to continue to take your medication.

Adults

Prevention of CMV disease in transplant patients

You should start to take this medicine within 10 days of your transplant. The usual dose is 900 mg Valcyte solution taken ONCE daily. Use the dispenser provided to take two 9 ml (450 mg) amounts (i.e. 2 dispensers filled to 9 ml (450 mg) graduation) of solution. You should continue with this dose for up to 100 days. If you have received a kidney transplant, your doctor may advise you to take the dose for 200 days.

Treatment of active CMV retinitis in AIDS patients (called induction treatment)

The usual dose is 900 mg of Valcyte solution taken TWICE a day for 21 days (three weeks). Use the dispenser provided and take two 9 ml (450 mg) amounts (i.e. 2 dispensers filled to 9 ml (450 mg) graduation) of the solution in the morning and two 9 ml (450 mg) amounts (i.e. 2 dispensers filled to 9 ml (450 mg) graduation) in the evening.

Do not take this dose for more than 21 days unless your doctor tells you to, as this may increase your risk of possible side effects.

Longer term treatment to prevent recurrence of active inflammation in AIDS patients with CMV retinitis (called maintenance treatment)

The usual dose is 900 mg Valcyte solution taken ONCE daily. Use the dispenser provided and take two 9 ml (450 mg) amounts of solution (i.e. 2 dispensers filled to 9 ml (450 mg) graduation). You should try to take the solution at the same time each day. Your doctor will advise you how long you should continue to take Valcyte. If your retinitis worsens while you are on this dose, your doctor may tell you to repeat the induction treatment (as above) or may decide to give you a different medicine to treat the CMV infection.

Elderly patients

Valcyte has not been studied in elderly patients.

Patients with kidney problems

If your kidneys are not working properly, your doctor may instruct you to take a lower dose of Valcyte solution each day. It is **very important** that you follow the dose prescribed by your doctor.

Patients with liver problems

Valcyte has not been studied in patients with liver problems.

Use in children and adolescents

Prevention of CMV disease in transplant patients

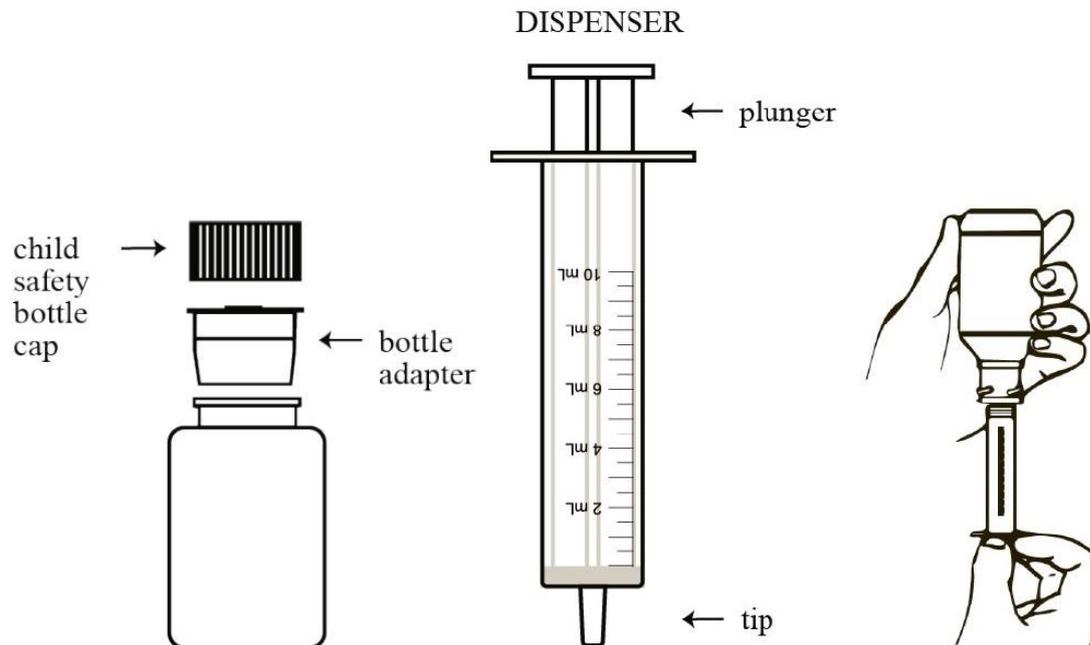
Children should start to take this medicine within 10 days of their transplant. The dose given will vary depending on the size of the child and should be taken ONCE daily. Your doctor will decide the most appropriate dose based on your child's height, weight and renal function. You should continue with this dose for up to 100 days. If your child has received a kidney transplant, your doctor may advise you to take the dose for 200 days.

Use the dispensers provided in the pack to measure the dose of Valcyte solution.

Method and route of administration

It is recommended that the Valcyte solution be prepared by the pharmacist prior to it being provided to you.

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 (see diagram).

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.

Care should be taken to avoid contact of the skin with the solution. If such contact occurs, wash thoroughly with soap and water.

Do not use the solution after the expiry date which is 49 days from the day of preparation.

If you take more Valcyte than you should

Contact your doctor or hospital immediately if you have taken, or think that you have taken, more Valcyte solution than you should. Taking more than the recommended dose can cause serious side effects, particularly affecting your blood or kidneys. You may need hospital treatment.

If you forget to take Valcyte

If you forget to take your dose of Valcyte take the missed dose as soon as you remember and take the next dose at the usual time. Do not take a double dose to make up for a missed dose.

If you stop taking Valcyte

You must not stop taking your medicine unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions

Up to 1 in every 1,000 people may have a sudden and severe allergic reaction to valganciclovir (anaphylactic shock). **STOP** taking Valcyte and go to the accident and emergency department at your nearest hospital if you experience any of the following:

- a raised, itchy skin rash (hives)
- sudden swelling of the throat, face, lips and mouth which may cause difficulty swallowing or breathing
- sudden swelling of the hands, feet or ankles

Serious side effects

Tell your doctor straight away if you notice any of the following serious side effects – your doctor may tell you to stop taking Valcyte and you may need urgent medical treatment:

Very common: may affect more than 1 in 10 people

- low white blood cell counts – with signs of infection such as sore throat, mouth ulcers or a fever
- low red blood cell counts – signs include feeling short of breath or tired, palpitations or pale skin

Common: may affect up to 1 in 10 people

- blood infection (sepsis) – signs include fever, chills, palpitations, confusion and slurred speech
- low level of platelets – signs include bleeding or bruising more easily than usual, blood in urine or stools or bleeding from gums, the bleeding could be severe
- severely low blood cell count
- pancreatitis – signs are severe stomach pain which spreads into your back
- fits

Uncommon: may affect up to 1 in 100 people

- failure of the bone marrow to produce blood cells
- hallucinations – hearing or seeing things that are not real
- abnormal thoughts or feelings, losing contact with reality
- failure of kidney function

The side effects that have occurred during treatment with valganciclovir or ganciclovir are given below.

Other side effects

Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

Very common: may affect more than 1 in 10 people

- thrush and oral thrush
- upper respiratory tract infection (e.g. sinusitis, tonsillitis)
- loss of appetite
- headache
- cough
- feeling short of breath
- diarrhoea
- feeling or being sick
- abdominal pain
- eczema
- feeling tired
- fever.

Common: may affect up to 1 in 10 people

- influenza
- urine infection – signs include fever, passing urine more often, pain when passing urine
- infection of the skin and the tissues under the skin
- mild allergic reaction – the signs may include red, itchy skin
- weight loss
- feeling depressed, anxious or confused
- trouble sleeping
- hands or feet feeling weak or numb, which may affect your balance
- changes to your sense of touch, tingling, tickling, pricking or burning feeling
- changes to the way things taste
- chills
- eye inflammation (conjunctivitis), eye pain or sight problems
- ear pain
- low blood pressure, which may make you feel dizzy or faint
- problems swallowing
- constipation, wind, indigestion, stomach pain, swelling of the abdomen
- mouth ulcers
- abnormal results of liver and kidney laboratory tests
- night sweats
- itching, rash
- hair loss
- back pain, muscle or joint pain, muscle spasms
- feeling dizzy, weak or generally unwell

Uncommon: may affect up to 1 in 100 people

- feeling agitated
- tremor, shaking

- deafness
- uneven heartbeat
- hives, dry skin
- blood in urine
- infertility in men – see ‘Pregnancy, breast-feeding and fertility’ section
- chest pain

Separation of the inner lining of the eye (detached retina) has only happened in AIDS patients treated with Valcyte for CMV infection.

Additional side effects in children and adolescents

The side effects reported in children and adolescents are similar to the side effects reported for adults.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance

Website: www.hpra.ie

5. How to store Valcyte

Keep this medicine out of the sight and reach of children.

Do not use the powder after the expiry date which is stated on the carton and bottle label (EXP). The expiry date refers to the last day of that month.

Powder: does not require any special storage condition.

Reconstituted solution: Store in a refrigerator (2°C - 8°C).

The shelf-life of the oral solution is 49 days. Do not use the solution 49 days after preparation or after the expiry date which will be written on the bottle by the pharmacist.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Valcyte contains

The active substance is valganciclovir hydrochloride. Following dissolution of the powder, 1 ml solution contains 55 mg valganciclovir hydrochloride corresponding to 50 mg valganciclovir as hydrochloride.

The other ingredients (excipients) are: povidone, fumaric acid, sodium benzoate (E211), sodium saccharin and mannitol, tutti-frutti flavour [maltodextrins (maize), propylene glycol, arabic gum E414 and natural identical flavouring substances mainly consisting of banana, pineapple and peach flavour].

What Valcyte looks like and contents of the pack

Valcyte powder is a granulate with a white to slightly yellow colour. A quantity of 12 g powder is supplied in a glass bottle. Upon reconstitution, the volume of the solution is 100 ml, providing a usable

volume of 88 ml. The solution is clear and colourless to brown. The pack also contains a bottle adapter and 2 dispensers that are graduated to 10 ml (500 mg), with 0.5 ml (25 mg) graduations.

Pack size: One bottle containing 12g powder.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

CHEPLAPHARM Arzneimittel GmbH
Ziegelhof 24
17489 Greifswald
Germany

Manufacturer

Roche Pharma AG
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D-79639 Grenzach-Wyhlen
Germany

Prestige Promotion Verkaufsförderung & Werbeservice GmbH
Lindigstrasse 6
63801 Kleinstheim
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Prestige Promotion Verkaufsförderung & Werbeservice GmbH
Borsigstrasse 2
63755 Alzenau
Germany

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Valcyte: Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Finland, Germany, Greece, Hungary, Iceland, Ireland, Italy, Liechtenstein, Lithuania, Luxembourg, The Netherlands, Norway, Poland, Slovenia, Spain, Sweden, United Kingdom (Northern Ireland)

RoValcyte: France, Portugal

This leaflet was last revised in October 2022.

Other sources of information

Detailed information on this medicine is available on:

Health Products Regulatory Authority (HPRA) website: <http://www.hpra.ie>

The following information is intended for healthcare professionals only:

It is recommended that the Valcyte solution be prepared by a pharmacist as follows:

1. Measure 91 ml of water in a graduated cylinder.
2. Remove the child resistant cap, add the water to the bottle, close the bottle with the child resistant cap and shake the closed bottle until the powder is dissolved.

3. Remove the child resistant cap and push the bottle adapter into the neck of the bottle.
4. Close the bottle with child resistant cap tightly to assure the proper seating of the bottle adapter in the bottle and child resistant status of the cap.
5. Write the date of expiration of the solution on the bottle label.

Wearing disposable gloves is recommended during reconstitution and when wiping the outer surface of the bottle/cap and the table after reconstitution.

Avoid inhalation or direct contact of skin or mucous membranes with the powder and direct contact with the solution. If contact occurs, wash thoroughly with soap and water; rinse eyes with plain water.