

PACKAGE LEAFLET: INFORMATION FOR THE USER

Valcyte[®] 450 mg film-coated tablets

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 tablets, 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 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 or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to ganciclovir, acyclovir or valaciclovir, which are medicines used to treat other virus infections.
- if you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Valcyte.

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 tablets and more tests will be done while you are taking the tablets.
- if you are having radiotherapy or haemodialysis
- 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.
- if you are currently taking ganciclovir capsules and your doctor wants you to switch to Valcyte tablets. It is important that you do not take more than the number of tablets prescribed by your doctor or you could risk an overdose.

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, tenofovir, abacavir, emtricitabine or similar kinds of drugs used to treat AIDS
- ribavirin, pegylated interferons, adefovir and entecavir used to treat Hepatitis B/C
- probenecid (a medicine against gout). Taking probenecid and Valcyte at the same time could increase the amount of ganciclovir in your blood

- mycophenolate mofetil (used after transplantations)
- vincristine, vinblastine, adriamycin, hydroxyurea or similar kinds of drugs to treat cancer
- cidofovir or foscarnet used against viral infections
- trimethoprim, trimethoprim/sulpha combinations and dapsone (antibiotics)
- 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 to take your tablets.

Women of childbearing age must use effective contraception when taking Valcyte.

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.

3. HOW TO TAKE VALCYTE

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

You have to be careful when handling your tablets. Do not break or crush them. You should swallow them whole and with food whenever possible. If you 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 with sterile water or clean water if you do not have sterile water.

You must stick to the number of tablets as instructed by your doctor to avoid overdose.

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

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 two tablets taken ONCE daily. You should continue with this dose for up to 100 days following your transplant. If you have received a kidney transplant, your doctor may advise you to take the tablets for 200 days.

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

The usual dose of Valcyte is two tablets taken TWICE a day for 21 days (three weeks). 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 two tablets taken ONCE daily. You should try to take the tablets 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 fewer tablets each day or only to take your tablets on certain days each week. It is **very important** that you only take the number of tablets 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.

For children who are unable to swallow Valcyte film-coated tablets, Valcyte powder for oral solution can be used.

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 tablets than you should. Taking too many tablets 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 tablets 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 the forgotten tablets.

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 100 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.

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

Very common side effects (may affect more than 1 in 10 users):

- Effects on the blood: a reduction in the number of white blood cells in the blood (neutropenia) - which will make you more likely to get infections, a reduction in the pigment in the blood that carries oxygen (anaemia) - which can cause tiredness and breathlessness when you exercise
- Effects on breathing: feeling short of breath or having trouble breathing (dyspnoea)
- Effects on the stomach and digestive system: diarrhoea

Common side effects (may affect 1 to 10 users in 100):

- Effects on the blood: a reduction in the number of leucocytes (blood cells that fight infection) in the blood (leucopenia), a reduction in the number of platelets in the blood (thrombocytopenia) - which can cause bruising and bleeding, a reduction in the number of several types of blood cells at the same time (pancytopenia)
- Effects on the nervous system: headache, difficulty sleeping (insomnia), strange tastes (dysgeusia), becoming less sensitive to touch (hypoesthesia), prickly or tingling skin (paraesthesia), loss of feeling in the hands or feet (peripheral neuropathy), dizziness, fits (convulsions)
- Effects in the eye: eye pain, swelling within the eye (oedema), separation of the inner lining of the eye (detached retina), seeing floaters
- Effects in the ear: earache
- Effects on breathing: coughing
- Effects on the stomach and digestion: feeling and being sick, stomach ache, constipation, wind, indigestion (dyspepsia), difficulty swallowing (dysphagia)
- Effects on the skin: inflamed skin (dermatitis), itching (pruritis), sweating at night
- Effects on the muscles, joints or bones: back pain, pain in the muscles (myalgia) or joints (arthralgia), stiff muscles (rigor), muscle cramps
- Infections: fungal infection in the mouth (oral candidiasis), infections caused by bacteria or viruses in the blood, inflammation of cellular tissue (cellulitis), inflammation or infection of the kidneys or bladder
- Effects in the liver: a rise in some liver enzymes, which will only be seen during blood tests
- Effects in the kidney: changes to the normal working of the kidneys
- Effects on eating: loss of appetite (anorexia), weight loss
- General effects: tiredness, fever, pain, chest pain, loss of energy (asthenia), generally feeling unwell (malaise)
- Effects on mood or behaviour: depression, feeling anxious, confused, having unusual thoughts

Uncommon side effects (may affect 1 to 10 users in 1000):

- Effects in the heart: changes to the normal heart beat (arrhythmia)
- Effects on circulation: low blood pressure (hypotension), which can cause you to feel light headed or faint

- Effects on the blood: a decrease in the production of blood cells in the bone marrow
- Effects in the nerves: shaking or trembling (tremor)
- Effects in the eyes: red, swollen eyes (conjunctivitis), abnormal vision
- Effects in the ears: deafness
- Effects on the stomach or digestion: swollen stomach, mouth ulcers, inflammation of the pancreas (pancreatitis) where you may notice severe pain in the stomach and back
- Effects on the skin: hair loss (alopecia), itchy rash or swellings (urticaria), dry skin
- Effects in the kidneys: blood in the urine (haematuria), kidney failure
- Effects in the liver: a rise in the liver enzyme called alanine aminotransferase (which will only be seen during blood tests)
- Effects on fertility: infertility in men
- Effects on mood or behaviour: having unusual changes in mood and behaviour, losing contact with reality such as hearing voices or seeing things that are not there, feeling agitated

Rare side effects (may affect 1 to 10 users in 10,000):

- Effects on the blood: failure of the production of all types of blood cells (red blood cells, white blood cells and platelets) in the bone marrow

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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE VALCYTE

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

Do not use this medicine after the expiry date, which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month. This medicine does not require any special storage conditions. Do not throw away any 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 450 mg of valganciclovir, present as 496.3 mg of valganciclovir hydrochloride.
- The other ingredients (excipients) in the tablet are Povidone K30, crospovidone, microcrystalline cellulose and stearic acid. The ingredients in the film-coat are hypromellose, titanium dioxide (E171), macrogol 400, red iron oxide (E172) and polysorbate 80.

What Valcyte looks like and contents of the pack

Valcyte tablets are pink oval film-coated tablets marked "VGC" on one side and "450" on the other side.

They are packed in bottles containing 60 film-coated tablets.

Manufacturer:

Roche Products Limited, 6 Falcon Way, Shire Park, Welwyn Garden City AL7 1TW, United Kingdom or Roche Pharma AG, Emil Barrell Strasse 1-Grenzach-Whylen, Germany or Recordati Industria Chimica e Farmaceutica S.p.A. – Via M. Civitali, 1 – 20148 Milano, Italy

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

Parallel Product Authorisation number:

PPA 465/221/1

This medicinal product is authorised in the Member States of the EEA under the following names:

Valcyte: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom
France, Portugal - RoValcyte

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