

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

**Valcyte®****450 mg**

Film-coated tablets

**Composition:**

Each tablet contains:

Valganciclovir 450 mg

\* For information on inactive ingredients, see section 6 "Further Information".

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. Keep this leaflet; you may need to read it again.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

If you have any side effects, refer to the doctor or pharmacist. This includes possible side effects not detailed in this leaflet (see section 4 "Side effects").

This medicine is not intended for treatment of adolescents, children and infants.

**IMPORTANT INFORMATION FOR YOUR REVIEW**

- Adherence to the doctor's instructions (dosage, directions for use, and duration of treatment) increases the chance of success of the treatment. In any case, do not stop treatment without consulting the attending doctor. Please review sections 2, 3 and 4 for detailed safety information.
- Do not use the medicine if you are breast-feeding. For information regarding pregnancy and breast-feeding in women treated with the medicine and in female partners of men treated with the medicine, see section 2, subsection "Pregnancy and breast-feeding".
- Store the medicine below 30°C.

**1) WHAT IS THE MEDICINE INTENDED FOR?****Valcyte®** is intended for treatment of cytomegalovirus infection of the retina (CMV retinitis) in patients with acquired immunodeficiency syndrome (AIDS).**Valcyte®** is intended for prevention of cytomegalovirus (CMV) disease in patients not infected with CMV, who have received an organ(s) donation by somebody carrying the virus.**Therapeutic group:****Valcyte®** belongs to a group of medicines that directly act to prevent the growth of viruses (antivirals). In the body, the active ingredient valganciclovir is changed into ganciclovir, a substance that prevents the cytomegalovirus (CMV) from multiplying and invading healthy cells. In patients with a weakened immune system, CMV may cause an infection in the body's organs which can be life-threatening.**2) BEFORE USING THE MEDICINE****❗ Do not use the medicine if:**

- you are sensitive (allergic) to the active ingredient valganciclovir, ganciclovir or to any of the additional ingredients contained in the medicine (see section 6 "Further Information").
- you are breast-feeding.

**⚠ Special warnings regarding use of the medicine****Do not use the medicine without consulting the doctor before starting treatment:**

- If you are sensitive (allergic) to acyclovir, penciclovir, valganciclovir or famciclovir, which are medicines intended for the treatment of other viral infections.
- If you have low levels in your blood of white blood cells, red blood cells or platelets (cells involved in blood clotting). The attending doctor will carry out blood tests before you start treatment with **Valcyte®** and more blood tests will be carried out during the course of treatment.
- If you are being treated with radiotherapy (medical treatment of a disease by radiation) or haemodialysis.
- If you suffer from a kidney problem. The doctor may recommend taking a lower dosage and there may be a need to carry out frequent blood tests during the course of treatment.
- If you are taking ganciclovir capsules and your doctor wants to switch you over to **Valcyte®** treatment. It is important that you do not take more **Valcyte®** tablets than prescribed by the doctor, otherwise, you will be at risk of overdose.

**Valcyte® and other medicines:****If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.**If you are taking other medicines at the same time that you are taking **Valcyte®**, the combination can affect the amount of medicine that reaches the bloodstream or can have a harmful effect. In particular, inform the doctor or pharmacist if you are taking:

- imipenem-cilastatin (an antibiotic). Combining **Valcyte®** with this medicine may cause convulsions
- zidovudine, didanosine, lamivudine, stavudine, tenofovir, abacavir, emtricitabine or similar medicines used to treat acquired immunodeficiency syndrome (AIDS)
- adefovir, or any other medicine used to treat viral hepatitis B
- probenecid (a medicine for treatment of gout). Combining **Valcyte®** with this medicine may increase the level of ganciclovir in your blood
- mycophenolate mofetil, ciclosporin or tacrolimus (medicines given after transplantations);
- vincristine, vinblastine, doxorubicin, hydroxyurea or similar medicines, to treat cancer
- trimethoprim, trimethoprim/sulpha combinations, dapsone (antibiotics)
- pentamidine (a medicine to treat parasites or lung infections)
- flucytosine or amphotericin B (medicines to treat fungus)

**Use of Valcyte® and food**

If you are sensitive to any food or medicine, inform the doctor before taking the medicine.

Swallow the tablets whole with food as much as possible. If you are unable to eat for any reason, you should still take the medicine at the regular time.

**Pregnancy, breast-feeding and fertility**

- Do not use **Valcyte®** if you are pregnant, unless the attending doctor recommends it. If you are pregnant or are planning to become pregnant, inform the doctor. Treatment with **Valcyte®** during pregnancy may harm the unborn baby.
- Do not take **Valcyte®** if you are breast-feeding. If the attending doctor wants you to begin treatment with **Valcyte®**, you must stop breast-feeding before you start taking the tablets.
- Women of child-bearing age** must use effective contraception during the course of treatment with **Valcyte®** and for at least 30 days after termination of treatment.
- Men** whose female partner may become pregnant, must use condoms during the course of treatment with **Valcyte®** and must continue to use condoms for 90 days after termination of the treatment.

**Driving and using machines**Do not drive, use any tools or operate dangerous machinery while using **Valcyte®** if you feel dizzy, tired, shaky or confused while taking the medicine.**3) HOW SHOULD YOU USE THE MEDICINE?**

Always use this medicine according to the doctor's instructions. Consult with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only. **Do not exceed the recommended dose.****The usual dosage is generally:****Dosage for adults:****Prevention of CMV disease in transplant patients:**

Start treatment within 10 days of the transplant. The usual dosage is two tablets, taken together, once daily. Continue with this dosage for up to 100 days following the transplant.

**Initial treatment of active CMV retinitis in AIDS patients (induction treatment):** the usual dosage is 2 tablets, taken together, twice a day for 21 days (3 weeks). Do not take this dosage for more than 3 weeks, unless your doctor tells you to, as this may increase the risk of possible side effects.**Long-term treatment to prevent recurrence of active inflammation in AIDS patients with CMV retinitis (maintenance treatment):** the usual dosage is 2 tablets, taken together, once daily. You should try to take the tablets at the same time each day. The doctor will advise you regarding duration of the treatment with **Valcyte®**. If the ailment worsens during the course of treatment, the doctor may tell you to repeat the induction dosage detailed above, or may change the treatment.**Elderly patients**

Studies have not been conducted in order to assess how this medicine works in elderly patients.

**Patients with kidney problems**If your kidneys do not function properly, the doctor may instruct you to take a lower daily dosage or to only take the tablets on certain days of the week. It is **very important** to take the only number of tablets the doctor prescribed for you.**Patients with liver problems**

Studies have not been conducted in order to assess how this medicine works in patients with liver problems.

**Directions for use of the medicine:** Be careful when taking the tablets or upon any other contact with them. Do not crush, break or halve the tablets. Swallow the tablets whole with food, as much as possible.

If you accidentally touch damaged tablets, wash your hands thoroughly with soap and water. If powder from the tablets gets into your eyes, rinse them with sterile water or with clean water, if you do not have sterile water.

**Tests and follow-up** - see section 2, subsection "Do not use the medicine without consulting the doctor before starting treatment".**If you accidentally took a higher dosage** - Taking too high a dosage of **Valcyte®** tablets may cause severe side effects that particularly affect the kidneys and blood system. Hospital treatment may be required. Therefore, if you took an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.**If you forget to take this medicine at the required time**, take a dose as soon as you remember and take the next dose at the usual time. Never take two doses together to compensate for a forgotten dose.

Adhere to the treatment as recommended by the attending doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with the doctor or pharmacist!

**Do not take medicines in the dark!** Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of this medicine, consult the doctor or pharmacist.

**4) SIDE EFFECTS**

As with any medicine, use of this medicine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Allergic reactions**Up to one in 1000 patients may experience a sudden and severe allergic reaction to valganciclovir (anaphylactic shock). **Stop treatment and proceed immediately to the nearest hospital emergency room if you notice any of the following effects:**

- a raised, itchy skin rash (may be a sign of 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 side effects (may affect more than 1 in 10 people):**

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

**Common side effects (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 the gums, the bleeding could be severe
- severely low blood cell count
- pancreatitis – signs are severe stomach pain, which spreads into the back
- fits

**Uncommon side effects (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, loss of contact with reality
- failure of kidney function

Below are side effects that have occurred during treatment with valganciclovir or ganciclovir:

**Additional side effects**

Inform the doctor if you notice any of the following side effects:

**Very common side effects (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 side effects (may affect up to 1 in 10 people):**

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

**Uncommon side effects (may affect up to 1 in 100 people):**

- feeling agitated
- tremor
- deafness
- heart rate disturbances
- 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 (retinal detachment) has only occurred in patients with acquired immunodeficiency syndrome (AIDS) who received **Valcyte®** for treatment of CMV.

If one of the above listed side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor or pharmacist immediately.

**Reporting side effects**Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>**5) HOW SHOULD THE MEDICINE BE STORED?**

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor. Do not store different medicines in the same package.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not discard medicines into the sink or household waste. Ask the pharmacist how to dispose of medicines no longer needed.

**6) FURTHER INFORMATION**

The active ingredient in the medicine is valganciclovir 450 mg, supplied as 496.3 mg valganciclovir hydrochloride.

In addition to the active ingredient, the medicine also contains: Povidone K30, crospovidone, microcrystalline cellulose, stearic acid powder, hypromellose, titanium dioxide, macrogol 400, red iron oxide and polysorbate 80.

**What the medicine looks like and the contents of the package:****Valcyte®** tablets are elongated, film-coated, pink-coloured tablets. "VGC" is imprinted on one side of the tablet and "450" is imprinted on the other side. The tablets are packaged in a bottle containing 60 film-coated tablets.**License holder and address:** Roche Pharmaceuticals (Israel) Ltd., P.O.B. 6391, Hod Hasharon 4524079.**Manufacturer and address:** F. Hoffmann-La Roche Ltd., Basel, Switzerland.**The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health in August 2014, and updated in December 2017 in accordance with the Ministry of Health guidelines****Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 127.70.30650.00