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

The medicine is dispensed with a doctor's prescription only

Valganciclovir Teva®

Film-coated tablets

Composition:
Each film-coated tablet contains:
Valganciclovir (as hydrochloride) 450 mg

For the list of inactive ingredients in the preparation 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 to treat 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).
This medicine is intended for the treatment of adults over the age of 18.

1. WHAT IS THE MEDICINE INTENDED FOR?

Valganciclovir Teva® is intended for the treatment of cytomegalovirus infections of the retina (CMV retinitis) in patients with acquired immunodeficiency syndrome (AIDS).
Valganciclovir Teva® is intended for prevention of cytomegalovirus (CMV) disease in patients not infected with CMV who have received an organ(s) donation from a person carrying the virus.

Therapeutic group:
Valganciclovir Teva® belongs to a group of medicines (antivirals) that directly act to prevent proliferation of viruses. In the body, valganciclovir, the active ingredient of the medicine, turns into ganciclovir.
Ganciclovir prevents a virus called cytomegalovirus from multiplying and penetrating healthy cells. In patients with a weakened immune system, cytomegalovirus 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, or to any of the other ingredients contained in the medicine (see section 6 "Further Information").
- Sensitive (allergic) to ganciclovir, aciclovir or to valaciclovir, which are medicines intended for the treatment of other viral infections.
- Breastfeeding.

Special warnings regarding use of the medicine

❗ Do not use the medicine without consulting the doctor before starting treatment:
- If you have low levels of white blood cells, red blood cells or platelets (cells involved in blood clotting) in your blood. The attending doctor will carry out blood tests before you start treatment with Valganciclovir and additional blood tests will be carried out during the course of treatment with the medicine.
- If you are being treated with radiotherapy (radiation therapy) or hemodialysis.
- If you are suffering from a kidney problem. The doctor may recommend that you take a lower dose and you may be required to perform frequent blood tests during the course of treatment.
- If you are currently taking ganciclovir and your doctor wants to switch you over to Valganciclovir treatment. It is important that you do not take more Valganciclovir tablets than prescribed for you by the doctor, otherwise, you may be at risk of overdose.

The preparation contains lactose (approximately 7 mg per tablet) and may cause an allergic reaction in people sensitive to this substance.

❗ **Valganciclovir Teva® 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 Valganciclovir, the combination can affect the amount of medicine that will reach your bloodstream or can have harmful effects. Inform the doctor or pharmacist if you are taking medicines that contain the following substances:
- imipenem-cilastatin (an antibiotic). Combining Valganciclovir with this medicine may cause convulsions.
- zidovudine, didanosine, lamivudine, tenofovir, abacavir, emtricitabine or similar medicines used to treat acquired immunodeficiency syndrome (AIDS).
- ribavirin, long-acting interferon (pegylated interferons), adefovir and entecavir, used to treat viral hepatitis B or C.
- probenecid (a medicine for treatment of gout). Concurrent use of Valganciclovir and this medicine may increase the level of ganciclovir in your blood.
- mycophenolate mofetil (a medicine given after transplantations).
- vincristine, vinblastine, adriamycin, hydroxyurea or similar medicines used to treat cancer.
- cidofovir or foscarnet used to treat viral infections.
- trimethoprim, a combination of trimethoprim with sulpha, dapsone (antibiotics).
- pentamidine (a medicine to treat parasites or lung infections).
- flucytosine or amphotericin B (antifungals).

Ask the doctor or pharmacist before taking any medicine.

❗ **Use of Valganciclovir Teva® and food**
If you are sensitive to any food or medicine, inform the doctor before taking the medicine.
Swallow the tablets whole with food, whenever possible. If you are unable to eat for any reason, you should still take the medicine as usual.

❗ **Pregnancy, breastfeeding and fertility**
- Do not use Valganciclovir if you are pregnant, unless the attending doctor recommends it. If you are pregnant or are planning to become pregnant, inform the doctor. Taking Valganciclovir during pregnancy could harm the unborn baby.
- Do not take Valganciclovir if you are breastfeeding. If the attending doctor wants you to begin treatment with Valganciclovir, you must stop breastfeeding before you start taking the tablets.
- Women of child-bearing age must use effective contraception during the course of treatment with Valganciclovir.
- Men whose female partner can become pregnant must use condoms during the course of treatment with Valganciclovir and must continue using condoms for 90 days after termination of the treatment.

❗ **Driving and using machines**
Do not drive, use any tools or operate dangerous machines while using Valganciclovir if you feel dizzy, tired, feel unstable or confused while using the medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine in accordance with the doctor's instructions. Consult the doctor or pharmacist if you are uncertain.
Exercise caution when touching the tablets. Do not halve, break or crush them. Swallow the tablets whole with food, whenever possible.
If you accidentally touched tablets that were damaged, wash your hands thoroughly with water and soap. If any powder from the tablets penetrated your eyes, wash them with sterile water, or with clean water if you do not have sterile water.
The dosage and treatment regimen will be determined by the doctor only.
Do not exceed the recommended dose.

The usual dosage is generally:
Adults
For prevention of cytomegalovirus (CMV) disease in patients who have undergone a transplant
Start treatment within 10 days from the date of the transplant. The usual dosage is 2 Valganciclovir tablets, taken together, once daily. Continue with this dosage for a period of up to 100 days following the transplant.
If you underwent a kidney transplant, the attending doctor may instruct you to take the tablets for 200 days.
Treatment of cytomegalovirus of the retina (CMV retinitis) in AIDS patients
- **Initial treatment of an active infection (induction treatment)**
  The usual dosage is 2 Valganciclovir tablets, taken together, twice a day for a duration of 21 days (3 weeks).
  Do not take this dosage for more than 3 weeks unless your doctor instructs 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 the preparation. If the ailment worsens during the course of treatment, the doctor may instruct you to start taking the aforementioned dosage of the induction treatment again, or decide to change the treatment.

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

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

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

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

Tests and follow-up
See section 2, subsection "Do not use the medicine without consulting the doctor before starting treatment".

If you took an overdose, if you think you took more tablets than required, or if a child accidentally swallowed the medicine, immediately refer to the attending doctor or proceed to a hospital emergency room and bring the package of the medicine with you.
Taking too high a dosage of Valganciclovir tablets may cause severe side effects that particularly affect the kidneys and blood system. Hospital treatment may be required.

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 regimen 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 100 patients may experience a sudden and severe allergic reaction to Valganciclovir (anaphylactic shock). Discontinue use of Valganciclovir and proceed immediately to the nearest hospital emergency room, if you notice any of the following effects:
- 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, legs or ankles.

Additional side effects
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), an effect which increases the risk of getting infections; a reduction in the pigment that carries oxygen in the blood (anemia), an effect which may cause tiredness and breathlessness on exertion.
- Effects on breathing: feeling short of breath or difficulty breathing (dyspnea).
- Effects on the stomach and digestive system: diarrhea.

Common side effects (may affect 1 to 10 in 100 users):
- Effects on the blood: a reduction in the number of leukocytes (blood cells which fight infections) in the blood (leukopenia), a reduction in the number of platelets in the blood (thrombocytopenia), an effect which may cause injuries and bleeding, a simultaneous reduction in the number of different types of blood cells (pancytopenia).
- Effects on the nervous system: headaches, difficulty sleeping, strange tastes in the mouth, reduced sensitivity to touch, prickly or tingling skin, loss of feeling in the hands or feet, dizziness, fits.
- Effects on the eyes: eye pain, swelling within the eye (edema), separation of the inner layer of the eye (detached retina), seeing floating spots in the eye.
- Effects on the ears: earache.
- Effects on breathing: cough.
- Effects on the stomach and digestion: nausea, vomiting, stomach ache, constipation, flatulence, indigestion, difficulty swallowing.
- Effects on the skin: inflammation of the skin (dermatitis), itching, night sweats.
- Effects on the muscles, joints or bones: back pain, muscle or joint pain, stiff muscles, 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 on the liver: a rise in some liver enzymes, which will only manifest in blood tests.
- Effects on the kidneys: changes to the normal activity of the kidneys.
- Effects on eating: loss of appetite, weight loss.
- General effects: tiredness, pain, fever, chest pain, lack of energy, generally unwell feeling.
- Effects on mood or behavior: depression, feeling anxious, confusion and having uncharacteristic thoughts.

Uncommon side effects (may affect 1 to 10 in 1,000 users):
- Effects on the heart: changes in normal heart rate (arrhythmia).
- Effects on the blood system: low blood pressure, that may cause dizziness or fainting.
- Effects on the blood: a decrease in the production of blood cells in the bone marrow.
- Effects on the nervous system: tremor.
- Effects on the eyes: swollen and red eyes, vision disturbances.
- Effects on the ears: deafness.
- Effects on stomach and digestion: swollen stomach, mouth ulcers, inflammation of the pancreas which may be accompanied by severe pain in the stomach and back area.
- Effects on the skin: hair loss (alopecia), swelling or itchy rash (urticaria), dry skin.
- Effects on the kidneys: kidney failure, blood in the urine.
- Effects on the liver: a rise in the liver enzyme called alanine aminotransferase, which will only be manifested in blood tests.
- Effects on fertility: impaired fertility in men.
- Effects on mood or behavior: uncharacteristic changes in mood and behavior, loss of contact with reality (hallucinations, hearing and seeing), feeling of agitation.

Rare side effects (may affect 1 to 10 in 10,000 users):
- Effects on the blood: failure to produce all types of blood cells (red blood cells, white blood cells and platelets) in the bone marrow.

Separation of the inner layer of the eye (detached retina) occurred only in patients with acquired immunodeficiency syndrome (AIDS) who received Valganciclovir to treat a cytomegalovirus infection.

If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult your 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) 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, must 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.
Store in a dry place, below 25°C.
Store in the original package.
Do not dispose of medicines in the sink or household waste bin. Consult a pharmacist regarding how to dispose of medicines that are no longer needed.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Mannitol, microcrystalline cellulose, hypromellose 15Cp/hpmc 2910 (E464), crospovidone type A, lactose monohydrate, titanium dioxide (E171), magnesium stearate, colloidal anhydrous silica, triacetin (E1518) and red iron oxide (E172).

What the medicine looks like and the contents of the package:
Valganciclovir Teva® film-coated tablets are oval, pink tablets. "93" is debossed on one side of the film-coated tablets, and "5465" is debossed on the other side.

The film-coated tablets are packaged in several ways:
Plastic bottles containing 30 or 60 film-coated tablets and a desiccant (a plastic cylinder). Be sure to keep the desiccant in the bottle and to close the bottle tightly after each use. Can be used for up to 9 months after first opening the bottle, on the condition that the preparation has not yet expired.
In trays (blisters). 30 or 60 film-coated tablets per package.

Not all package forms and sizes may be marketed.

License Holder and its Address: Abic Marketing Ltd., P.O.B. 8077, Netanya

Manufacturer and its Address: Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petach-Tikva

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved in 11.2016

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 157.38.34391.00