

## **Package leaflet: Information for the user**

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

#### **1. What Valganciclovir is and what it is used for**

Valganciclovir 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.

Valganciclovir 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 Valganciclovir**

##### **Do not take Valganciclovir:**

- 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 Valganciclovir:

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

##### **Take special care with Valganciclovir**

- 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 Valganciclovir 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 Valganciclovir. 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 Valganciclovir**

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

If you take other medicines at the same time as taking Valganciclovir the combination could affect the amount of active substance 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 Valganciclovir can cause convulsions (fits)
- zidovudine, didanosine, lamivudine, stavudine, tenofovir, abacavir, emtricitabine or similar kinds of medicines used to treat AIDS
- adefovir or any other medicines used to treat Hepatitis B
- probenecid (a medicine against gout). Taking probenecid and Valganciclovir 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 medicines to treat cancer
- trimethoprim, trimethoprim/sulpha combinations and dapsone (antibiotics)
- pentamidine (medicine to treat parasite or lung infections)
- flucytosine or amphotericin B (anti-fungal agents)

### **Valganciclovir with food and drink**

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

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not take Valganciclovir if you are pregnant unless your doctor recommends it. Taking this medicine when you are pregnant could harm your unborn baby.

You must not take Valganciclovir if you are breast-feeding. If your doctor wants you to begin treatment with this medicine you must stop breast-feeding before you start to take your tablets.

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

Men whose partners could become pregnant should use condoms while taking Valganciclovir 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 Valganciclovir**

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.**

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

### **Use in adults:**

#### **Prevention of CMV disease in transplant patients**

You should start to take this medicine within 10 days of your transplant. The recommended 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 recommended dose Valganciclovir 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 recommended 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 Valganciclovir. 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**

Valganciclovir 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**

Valganciclovir 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 Valganciclovir film-coated tablets, the availability of valganciclovir powder for oral solution may be checked.

**If you take more Valganciclovir 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 Valganciclovir**

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 Valganciclovir**

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 Valganciclovir 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 Valganciclovir 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**

- 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**

- 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**

- feeling agitated
- tremor, shaking
- deafness
- uneven heartbeat
- hives, dry skin
- blood in urine
- infertility in men – see section 2, “Pregnancy, breast-feeding and fertility”
- chest pain

Separation of the inner lining of the eye (detached retina) has only happened in AIDS patients treated with valganciclovir 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 the Yellow Card Scheme (Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Valganciclovir

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 bottle and the 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 protect the environment.

## 6. Contents of the pack and other information

### What Valganciclovir contains

- The active substance is valganciclovir (as hydrochloride).  
Each film-coated tablet contains 496.3 mg of valganciclovir hydrochloride equivalent to 450 mg of valganciclovir.
- The other ingredients are  
Tablet core: Microcrystalline cellulose, Povidone (K 30), Crospovidone, Stearic Acid 50  
Coating medium (pink): Hypromellose, Titanium dioxide (E171), Macrogol 400, Red Iron Oxide (E172), Polysorbate 80

### What Valganciclovir looks like and contents of the pack

Valganciclovir 450 mg film-coated tablets are presented as pink oval biconvex film coated tablets embossed with “450” on one side with dimensions  $17.1 \pm 0.3$  mm in length,  $8.2 \pm 0.3$  mm in width and  $6.1 \pm 0.3$  mm in thickness.

They are packed in a cardboard box containing white opaque HDPE bottle with child-resistant polypropylene (PP) screw cap and induction seal liner.

Pack size: One bottle containing 60 film-coated tablets.

### Marketing Authorisation Holder

Glenmark Pharmaceuticals Europe Limited  
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