

**Patient Information Leaflet**  
**Valganciclovir 50 mg/ml powder for oral solution**  
{valganciclovir}

**Read all of this leaflet carefully before you start taking this product 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 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.

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 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 Valganciclovir**

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 Valganciclovir 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 Valganciclovir 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 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 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)

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

Valganciclovir 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**

You should not take Valganciclovir if you are pregnant unless your doctor recommends it. If you are pregnant or planning to become pregnant you must tell your doctor. Taking Valganciclovir 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 Valganciclovir you must stop breast-feeding before you start taking your medication.

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.

### **Valganciclovir 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 Valganciclovir**

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 Valganciclovir 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.**

Valganciclovir 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 Valganciclovir 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 Valganciclovir 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 Valganciclovir 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 Valganciclovir 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 Valganciclovir 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 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 a lower dose of Valganciclovir solution each day. It is **very important** that you follow the dose 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**

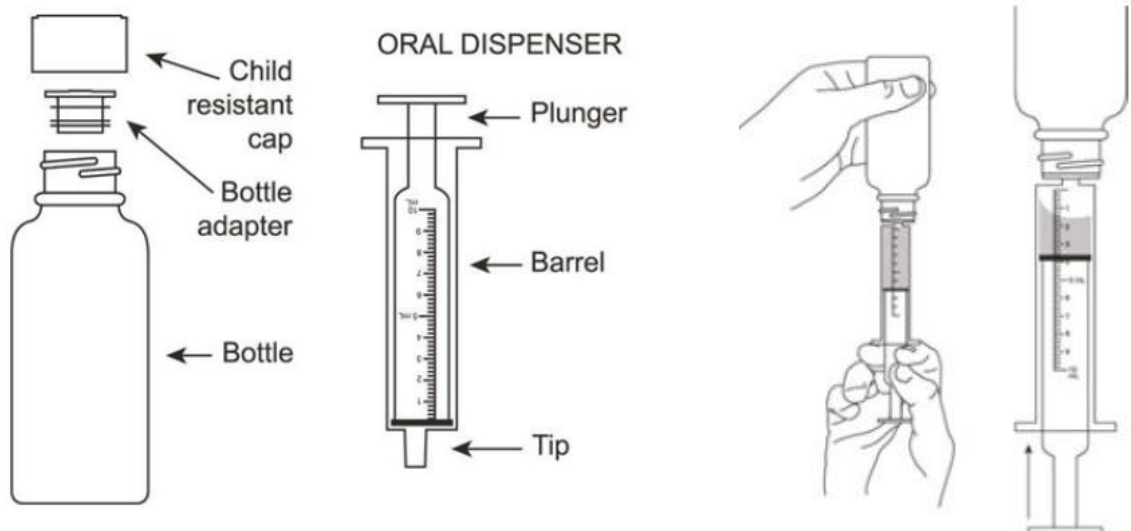
Children should start to take this medicine within 10 days of their transplant. The dose given will vary depending on the size of the child and should be taken ONCE daily. Your doctor will decide the most appropriate dose based on your child's height, weight and renal function. You should continue with 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.

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

#### **Method and route of administration**

It is recommended that the Valganciclovir 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 Valganciclovir than you should**

Contact your doctor or hospital immediately if you have taken, or think that you have taken, more Valganciclovir 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 Valganciclovir**

If you forget to take your dose of Valganciclovir 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 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 products, Valganciclovir 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:** 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 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.

If any of side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

## **5. How to store Valganciclovir**

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: Store below 25°C

Reconstituted solution: Store in a refrigerator (2°C - 8°C). Don't Freeze.  
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**

### **a. What Valganciclovir 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: sodium benzoate (E211), mannitol, Sucralose, Tartaric Acid and tutti-frutti flavor

**b. What Valganciclovir looks like and contents of the pack**

Valganciclovir powder is a granulate with a white to slightly yellow colour. A quantity of 12 g powder is supplied in a bottle. Upon reconstitution, the volume of the solution is 100 ml, providing a usable volume of 88 ml. The solution is clear and colorless to brown. The pack also contains a bottle adapter and dispensers that are graduated to 10 ml (500 mg), with 0.5 ml (25 mg) graduations.

Pack size: One bottle containing 12g powder.

**c. Marketing Authorization Holder and Manufacturer:**

Granules Pharmaceuticals Inc.  
Chantilly, VA 20151, USA

**d. This leaflet was approved in ( ), Version number ( ).**

**e. To report any side effect(s):**

- **Saudi Arabia:**

- The National Pharmacovigilance and Drug Safety Center (NPC)
  - Fax: +966 11 205 7662
  - SFDA Call Center: 19999
  - E-mail: npc.drug@sfda.gov.sa
  - Website: www.sfda.gov.sa

- **For other GCC states: please refer to the health authority in your region.**

**This is a medicament**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
  - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacists who sold the medicament.
  - The doctor and the pharmacists are experts in medicine, its benefits and risks.
  - Do not by yourself interrupt the period of treatment prescribed for you.
  - Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children

Council of Arab Health Ministers

**f. This patient information leaflet was approved by Saudi Food and Drug Authority.**