

Package leaflet: Information for the user

Valganciclovir Cipla 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 Cipla is and what it is used for
2. What you need to know before you take Valganciclovir Cipla
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1. What Valganciclovir Cipla 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 Cipla 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 Cipla

Do not take Valganciclovir Cipla:

- 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 Cipla.

- 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 Cipla 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 Cipla. 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 Cipla

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 Cipla 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 Cipla 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 Cipla 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 (antibiotics)
- pentamidine (drug to treat parasite or lung infections)
- flucytosine or amphotericin B (anti-fungal agents)

Valganciclovir Cipla with food and drink

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

Pregnancy, breast-feeding and fertility

You should not take Valganciclovir Cipla 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 Cipla when you are pregnant could harm your unborn baby.

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

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

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

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 Cipla 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 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 Cipla 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 Cipla. 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 Cipla 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 Cipla 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 Cipla, other pharmaceutical form may be checked for their availability, e. g. powder for oral solution.

If you take more Valganciclovir Cipla 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 Cipla

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 Cipla

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 Cipla 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 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

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, 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 side effects (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 ‘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.

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Valganciclovir Cipla

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 the month.

This medicinal product 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 Cipla contains

The active substance is valganciclovir. Each film-coated tablet contains valganciclovir hydrochloride equivalent to 450 mg of valganciclovir

The other ingredients are:

- Tablet core: cellulose microcrystalline, crospovidone (type B), povidone K30, stearic acid 50.
- Film coat: hypromellose, titanium dioxide (E171), macrogol, iron oxide red (E172).

What Valganciclovir Cipla looks like and contents of the pack

Valganciclovir Cipla are pink coloured, capsule shaped, biconvex film coated tablets plain on both sides.

Length: 17.10 ± 0.20 mm (16.90 – 17.30)

Breadth: 8.10 ± 0.20 mm (7.90 – 8.30)

White opaque, high density polyethylene (HDPE) bottle with child-resistant polypropylene closure (with liner), and rayon coil enclosed.

Pack size: 60 tablets

Aluminium/PVC/PE/PVDC blister packs

Pack size: 6 x 10 = 60 tablets

Marketing Authorisation Holder

<To be completed nationally>

Manufacturer

<To be completed nationally>

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

Sweden: Valganciclovir Cipla 450 mg filmdragerade tabletter

Norway: Valganciclovir Cipla

Finland: Valganciclovir Cipla 450 mg kalvopäällysteiset tabletit

Denmark: Valganciclovir Cipla

United Kingdom: Valganciclovir 450 mg film-coated tablets

Germany: Valganciclovir Cipla 450 mg Filmtabletten

France: Valganciclovir Cipla 450 mg, comprimé pelliculé

Spain: Valganciclovir Cipla 450 mg comprimidos recubiertos con película EFG

Italy: Valganciclovir Cipla 450 mg compresse rivestite con film

Poland: Valganciclovir Cipla, 450 mg, tabletki powlekane

Czech Republic: Valganciclovir Cipla 450 mg potahované tablety

Slovakia: Valganciclovir Cipla 450 mg filmom obalené tablety

Hungary: Valganciclovir Cipla 450 mg filmtabletta

Romania: Valganciclovir Cipla 450 mg comprimate filmate

Croatia: Valganciclovir Cipla 450 mg filmom obložene tablete

Netherland: Valganciclovir Cipla 450 mg filmomhulde tabletten

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