

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

1. What Valganciclovir tablet 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 tablet 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 tablets

Do not take Valganciclovir tablets:

- 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 tablets.

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

Take special care with Valganciclovir tablets:

- 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 tablets 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 tablets. 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 tablets

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 tablets 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 tablets 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 tablets 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 tablets with food and drink

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

Pregnancy, breast-feeding and fertility

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

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

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

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

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 tablets 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 usual 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 usual dose 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 usual 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 tablets. 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 tablet 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, a valganciclovir powder for oral solution can be used.

If you take more Valganciclovir tablets 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 tablets

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 tablet.

If you stop taking Valganciclovir tablets

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 1000 people may have a sudden and severe allergic reaction to valganciclovir (anaphylactic shock). **STOP** taking Valganciclovir tablets 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 tablets 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 ‘Fertility’ section
- chest pain

Separation of the inner lining of the eye (detached retina) has only happened in AIDS patients treated with Valganciclovir tablets 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

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Valganciclovir tablets

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 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 film-coated tablets contains

The active substance is 450 mg of valganciclovir, present as 496.3 mg of valganciclovir hydrochloride.

The other ingredients are:

Core: Microcrystalline cellulose; crospovidone type A, povidone (K-30) and stearic acid (50).

Coating: hypromellose 3 cP, hypromellose 6 cP, titanium dioxide (E 171), macrogol 400, iron oxide red (E172) and Polysorbate 80.

What Valganciclovir film-coated tablets looks like and contents of the pack

Valganciclovir film-coated tablet is presented as 450 mg film-coated tablets. The tablets are described below.

16.7 x 7.8 mm approx., pink, oval, biconvex film coated tablets debossed with 'J' on one side and '156' on the other side.

Valganciclovir film-coated tablet is available in

OPA-Aluminium-PVC/Aluminium blister, pack with an outer carton: 30, 60, 90 and 120 tablets.

High Density Polyethylene (HDPE) bottle filled with purified cotton with child-resistant polypropylene screw cap with pulp liner (made of backing, wax, foil, PET and heat seal): 60 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer

Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park, Paola
PLA 3000, Malta

Accord Healthcare Limited
Sage House, 319 Pinner Road, North Harrow,
Middlesex, HA1 4HF,
United Kingdom

Wessling Hungary Kft
Budapest, Fõti út 56,
1047, Hungary

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

| Name of member state | Name of medicinal product |
|-----------------------------|---|
| Netherland | Valganciclovir Accord 450 mg filmomhulde tabletten |
| Austria | Valganciclovir Accord 450 mg Filmtabletten |
| Cyprus | Valganciclovir Accord 450 mg Επικαλυμμένα με λεπτό υμένιο δισκία |
| Zech Republic | Virexan 450 mg |
| Denmark | Valganciclovir Accord 450 mg filmovertrukne tabletter |
| Estonia | Valganciclovir Accord |
| Finland | Valganciclovir Accord 450 mg tabletti, kalvopäällysteinen |
| Ireland | Valganciclovir 450 mg film-coated tablets |
| Italy | Valganciclovir Accord |
| Lithuania | Valganciclovir Accord 450 mg plėvele dengtos tabletės |
| Latvia | Valganciclovir Accord 450 mg apvalkotās tabletes |
| Malta | Valganciclovir 450 mg film-coated tablets |
| Norway | Valganciclovir Accord |
| Poland | Valhit |
| Portugal | Valganciclovir Accord |
| Sweden | Valganciclovir Accord 450 mg filmdragerade tabletter |
| United Kingdom | Valganciclovir 450 mg film-coated tablets |
| Spain | Valganciclovir Accord 450 mg comprimidos recubiertos con película |
| France | Valganciclovir Accord 450 mg comprimé pelliculé |

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