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.
- you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking valganciclovir:
- if you are allergic to azathioprine, mercaptopurine or thiopurine.
- if you are taking any of these medicines:
  - sulphasalazine, salazopyrine or other sulphasalazine derivatives
  - trimethoprim, trimethoprim/sulpha combinations and dapsone (antibiotics)

Talk to your doctor or pharmacist if you take other medicines at the same time as taking valganciclovir because:
- these medicines may harm them, even if their signs of illness are the same as yours.
- probenecid (a medicine against gout). Taking probenecid and valganciclovir at the same time could increase the amount of ganciclovir in your blood.
- sulphasalazine, salazopyrine or other sulphasalazine derivatives.
- rifampicin, rifabutin, rifapentine, rifapentine, isoniazid, pyrazinamide, cycloserine (antibiotics).
- oral ganciclovir is given to patients who have a lower risk of CMV infection.
- you should make sure that your doctor or pharmacist knows that you are taking these medicines at the same time:
  - if you are pregnant or planning to become pregnant you must tell your doctor.
  - if you are breast-feeding.
  - 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 frequency 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

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:

- aspirin
- ibuprofen
- other pain-relieving or anti-inflammatory medicines
- analgesics (including paracetamol and aspirin)
- salicylates
- ibuprofen
- naproxen
- any medicines used to treat HIV (AIDS) (e.g. protease inhibitors)
- other medicines that contain loxoribine (such as valaciclovir) and azidothymidine (AZT, zidovudine). If you are taking valganciclovir, your doctor may tell you to take your other medicines at a different time of day or give them to you at a different time of day.

Other medical conditions

If you have any medical conditions that may affect your ability to take valganciclovir, your doctor may advise you to take the tablets for 200 days.

Treatment of active CMV retinitis in AIDS patients (called induction treatment)

You should start to take this medicine within 10 days of your transplant.

If you have any medical conditions that may affect your ability to take valganciclovir, your doctor may advise you to take the tablets for 200 days.

The side effects reported in children and adolescents are similar to the side effects reported in adults.

If you have any medical conditions that may affect your ability to take valganciclovir, your doctor may advise you to take the tablets for 200 days.

Longer term treatment to prevent recurrence of active inflammation in AIDS patients with CMV retinitis (called maintenance treatment)

The usual dose is twice 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.

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 to only 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.

Valganciclovir should, wherever 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 twice tablets taken 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.

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

This includes:
- any medicines used to treat viral infections.
- acetaminophen
- antituberculosis drugs
- antiviral drugs
- corticosteroids
- corticotropin (adrenocorticotropin)
- emtricitabine or similar kinds of drugs used to treat AIDS
- interferon alfa, interferon gammas
- lopinavir
- methotrexate
- any medicine obtained without a prescription.

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If you have received a kidney transplant, your doctor may advise you to take the tablets for 200 days.

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If you have any medical conditions that may affect your ability to take valganciclovir, your doctor may advise you to take the tablets for 200 days.

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Patients with liver problems

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Valganciclovir should, wherever possible, be taken with food - see section 2.

Adults:

Prevention of CMV disease in transplant patients

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If you have received a kidney transplant, your doctor may advise you to take the tablets for 200 days.

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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 to only 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.
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.
For the treatment of CMV-infections of the retina of the eye in adult patients with a weakened immune system, CMV can cause an infection in the body’s cytomegalovirus (CMV) from multiplying and invading healthy cells. In patients with acquired immunodeficiency syndrome (AIDS). CMV-infection of the upper respiratory tract (e.g. sinusitis, tonsillitis)

3. How to take valganciclovir

3.1. Adult patients

Patients with kidney problems
Valganciclovir has not been studied in elderly patients.

3.3. Children

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.

4. Possible side effects

4.1. Very common effects

4.3. Rare effects

4.5. Very rare effects

4.6. In children and adolescents

4.7. Overdose

5. How to store valganciclovir

5.1. Keep this medicine out of the sight and reach of children.

6. Contents of the pack and other information

6.1. What valganciclovir contains

The active substance is 450 mg of valganciclovir, present as 496.3 mg of ganciclovir hydrochloride. The ingredients in the tablet are Povidone (K-30), crospovidone (Type A), cellulose microcrystalline (Avicel Type 101) and polyvinyl alcohol 50%. The ingredients in the film-coat are hypromellose (3 cP, 6 cP), titanium dioxide (E171), magnesium 400, iron oxide red (E172) and polyethylene 80. What valganciclovir looks like and contents of the pack

Valganciclovir 450 mg film-coated tablets are oval, biconvex, pink coloured film-coated tablets. They are packed in HDPE bottles containing 60 film-coated tablets.

Marketing Authorisation Holder
Zentiva Pharma UK Limited, 12 New Fetter Lane, London EC4A 1JP, United Kingdom

Manufacturer
S.C. Zentiva S.A., B-dul Theodor Pallady nr.50, sector 3, Bucharest cod 023266, Romania

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