2. What you need to know before you 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 breastfeeding.

Precautions and warnings

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.
- 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 bloodstream or cause harmful effects. Tell your doctor if you are already taking medicines that contain any of the following:

- isoniazid (an anti-tuberculosis medicine)
- rifampicin, pyrazinamide, ethambutol or cycloserine (antituberculosis medicines)
- rifabutin (a tuberculosis medicine)
- carbamazepine, phenobarbital or phenytoin (anticonvulsant medicines)
- indinavir, nelfinavir, ritonavir, saquinavir, lopinavir, fosamprenavir, atazanavir, tipranavir or darunavir (used to treat HIV or 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 organ 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)
- fluocytosine 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, breastfeeding and fertility

- If you are pregnant. 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 to prescribe it for you, you should still take your dose of valganciclovir as usual.
- If you have low numbers of white blood cells, red blood cells or platelets (small cells involved in fighting infection) 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 have any further questions on the use of this medicine, ask your doctor or pharmacist.
- If you have any side effects, ask your doctor or pharmacist.
- If you have any other questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may be harmful 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.
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 weight and renal function. You should continue with this dose for 3 weeks after transplantation. If you emotional or mental health has worsened after transplantation, 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 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 you should 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 rash, 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 this medicine and you may need urgent medical treatment:

Very common: may affect more than 1 in 10 people

• trouble sleeping
• low 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
• pancytopenia – signs are severe stomach pain which spreads into your back

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

• thirst and oral thirst
• 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
• feeling depressed, anxious or confused
• taste change
• hands or feet feeling weak or numb, which may affect your balance
• changes to your sense of touch, tingling, pricking, pinching or burning feeling
• changes to the things taste
• chill
• 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
• sleeplessness
• 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 any side effects directly via the Yellow Card Scheme at: 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 carton after EXP. The expiry date refers to the last day of that 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 contains

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

The other ingredients in the tablet are Povidone (K-30), croscarmellose (Type A), cellulose microcrystalline (Fipan Type 101) and stearic acid 50.

The ingredients in the film-coat are hypromellose (HP 65/68), titanium dioxide (E171), macrogol 400/ PEG, iron oxide red (E172) and polysorbate 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, One Onalow Street, Guildford, Surrey, GU1 4YS, UK

Manufacturer

S.C. Zentiva S.A., B-dul Theodor Pallady nr.50, sector 3, Bucuresti cod 032266, Romania

This leaflet was last revised in February 2018.

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