Package leaflet: Information for the patient

Valganciclovir Sandoz® 450 mg, filmomhulde tabletten

valganciclovir (as hydrochloride)

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 [Nationally completed name] is and what it is used for
2. What you need to know before you take [Nationally completed name]
3. How to take [Nationally completed name]
4. Possible side effects
5. How to store [Nationally completed name]
6. Content of the pack and other information

1. What [Nationally completed name] is and what it is used for

[Nationally completed name] 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.

[Nationally completed name] 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 [Nationally completed name]

Do not take [Nationally completed name]
- if you are allergic to valganciclovir, ganciclovir or any of the other ingredients of this medicine (listed in section 6).
- if you are breastfeeding.

Warnings and precautions
Talk to your doctor or pharmacist before taking [Nationally completed name].

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

Take special care with [Nationally completed name]
- 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 [Nationally completed name] 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 [Nationally completed name] 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 [Nationally completed name]
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 [Nationally completed name] 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 [Nationally completed name] 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 [Nationally completed name] at the same time could increase the amount of ganciclovir in your blood
- mycophenolate mofetil, ciclosporin or tacrolimus (**used after transplantations**)
- vincristine, vinblastine, doxorubicin, hydoxyurea 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**)

[Nationally completed name] with food and drink
[Nationally completed name] should be taken with food. If you are unable to eat for any reason, you should still take your dose of [Nationally completed name] as usual.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not take [Nationally completed name] if you are pregnant unless your doctor recommends it. If you are pregnant or planning to become pregnant you must tell your doctor.
Taking [Nationally completed name] when you are pregnant could harm your unborn baby.

You must not take [Nationally completed name] if you are breastfeeding. If your doctor wants you to begin treatment with [Nationally completed name] you must stop breastfeeding before you start to

take your tablets.

Women of childbearing age must use effective contraception when taking [Nationally completed name] and for at least 7 months after treatment has finished.

Men whose partners could become pregnant should use condoms while taking [Nationally completed name] and should continue to use condoms for 4 months 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 [Nationally completed name]

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.

[Nationally completed name] tablets should, whenever possible, be taken with food – see section 2.

Other suitable dosage forms are available for children and adolescents who need dose adjustments.

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 [Nationally completed name] 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 [Nationally completed name]. 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
[Nationally completed name] 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 [Nationally completed name] film-coated tablets, valganciclovir powder for oral solution can be used.

If you take more [Nationally completed name] 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 [Nationally completed name]
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 [Nationally completed name]
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 [Nationally completed name] 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 [Nationally completed name] 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.

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 [Nationally completed name]

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 blister, carton, or bottle after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage condition.

Shelf life after first opening:
Bottles: 2 months

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 protect the environment.

6. Content of the pack and other information

What [Nationally completed name] contains

The active substance is valganciclovir (as hydrochloride).
Each tablet contains 450 mg of valganciclovir (as hydrochloride).

The other ingredients are:
Tablet core: cellulose microcrystalline (PH101), crospovidone (Type A), povidone (K30), stearic acid 50
Film-coating: Opadry Pink 15B24005: hypromellose (E 464) (3 cP), hypromellose (E464) (6 cP), titanium dioxide (E 171), Macrogol 400 (E 1521), iron oxide red (E 172), polysorbate 80 (E 433)

What [Nationally completed name] looks like and contents of the pack

[Nationally completed name] are pink, oval, biconvex, film-coated tablets (16.7 x 7.8 mm), debossed with “J” on one side and “156” on the other side.

The film-coated tablets are packed in aluminium/PVC/aluminium/OPA blisters and inserted in a carton or packed in a HDPE bottle with a child resistant polypropylene screw cap with aluminium pulp liners and cotton enclosed.

Blister: 10, 30, 60, 90, 120 film-coated tablets
Bottle: 60 film-coated tablets

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikanten
Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

LEK S.A.
ul. Domaniewska 50 C
02-672 Warschau
Polen

Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

In het register ingeschreven onder:
Valganciclovir Sandoz 450 mg, filmomhulde tabletten is in het register ingeschreven onder RVG 114137.

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland:	Valganciclovir Sandoz 450 mg, filmomhulde tabletten
Oostenrijk:	Valganciclovir Sandoz 450 mg - Filmtabletten
België:	Valganciclovir Sandoz 450 mg filmomhulde tabletten
Kroatië:	Nyctos 450 mg filmom obložene tablete
Cyprus:	Valganciclovir HCl Sandoz 450 mg
Tsjechië:	Valganciclovir Sandoz 450 mg potahované tablety
Denemarken:	Valganciclovir Sandoz
Estland:	Valganciclovir Sandoz
Finland:	Valganciclovir Sandoz
Frankrijk:	VALGANCICLOVIR SANDOZ 450 mg, comprimé pelliculé
Duitsland:	Valganciclovir HEXAL 450 mg Filmtabletten
Griekenland:	Valganciclovir /Sandoz
Ierland:	Valganciclovir Rowex 450 mg Filmcoated tablets
Italië:	VALGANCICLOVIR SANDOZ
Letland:	Valganciclovir Sandoz 450 mg apvalkotās tabletes
Litouwen:	Valganciclovir Sandoz 450 mg plėvele dengtos tabletės
Luxemburg:	Valganciclovir Sandoz 450 mg comprimés pelliculés
Noorwegen:	Valganciclovir Sandoz
Polen:	Ceglar
Portugal:	Valganciclovir Sandoz
Roemenië:	VALGANCICLOVIR SANDOZ 450 mg comprimate filmate
Slovenië:	Valganciklovir Lek 450 mg filmsko obložene tablete
Spanje:	Valganciclovir Sandoz 450 mg comprimidos recubiertos con película EFG
Zweden:	Valganciclovir Sandoz
Verenigd Koninkrijk:	Valganciclovir 450mg Film-coated Tablets

Deze bijsluiter is voor het laatst goedgekeurd in september 2026.