

Package leaflet: Information for the patient

Valganciclovir Rowex 450 mg Film-coated tablets

Valganciclovir

ROWEX®

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

1 What Valganciclovir Rowex is and what it is used for

Valganciclovir Rowex 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 Rowex is used:

- for treatment of CMV-infections of the retina of the eye in 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 patients 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 Rowex**Do not take Valganciclovir Rowex**

- if you are allergic to valganciclovir or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to ganciclovir, acyclovir or valaciclovir, which are medicines used to treat other virus infections.
- if you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Valganciclovir Rowex.

- 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 Rowex 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 Rowex 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 Rowex

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 Rowex the combination could affect the amount of drug that gets into your bloodstream 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 Rowex can cause convulsions (fits)
- zidovudine, didanosine, lamivudine, tenofovir, abacavir, emtricitabine or similar kinds of **drugs used to treat AIDS**
- ribavirin, pegylated interferons, adefovir and entecavir used to treat Hepatitis B/C
- probenecid (a **medicine against gout**). Taking probenecid and Valganciclovir Rowex at the same time could increase the amount of ganciclovir in your blood
- mycophenolate mofetil (**used after transplantations**)
- vincristine, vinblastine, adriamycin, hydroxyurea or similar kinds of **drugs to treat cancer**
- cidofovir or foscarnet **used against viral infections**
- trimethoprim, trimethoprim/sulpha combinations and dapsone (**antibiotics**)
- pentamidine (**drug to treat parasite or lung infections**)
- flucytosine or amphotericin B (**anti-fungal agents**)

Valganciclovir Rowex with food and drink

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

Pregnancy and 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 Valganciclovir Rowex if you are pregnant unless your doctor recommends it. Taking Valganciclovir Rowex when you are pregnant could harm your unborn baby.

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

Women of childbearing age must use effective contraception when taking Valganciclovir Rowex.

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

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 Rowex 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 Valganciclovir Rowex 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 Rowex. 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 Rowex 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.

If you take more Valganciclovir Rowex 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 Rowex

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 Rowex

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.

continued on the next page >>

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 100 people may have a sudden and severe allergic reaction to valganciclovir (anaphylactic shock). **STOP** taking Valganciclovir Rowex 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.**

The side effects that have occurred during treatment with valganciclovir or ganciclovir are given below:

Very common (may affect more than 1 in 10 people):

- Effects on the blood: a reduction in the number of white blood cells in the blood (neutropenia) - which will make you more likely to get infections, a reduction in the pigment in the blood that carries oxygen (anaemia) - which can cause tiredness and breathlessness when you exercise
- Effects on breathing: feeling short of breath or having trouble breathing (dyspnoea)
- Effects on the stomach and digestive system: diarrhoea

Common (may affect up to 1 in 10 people):

- Effects on the blood: a reduction in the number of leucocytes (blood cells that fight infection) in the blood (leucopenia), a reduction in the number of platelets in the blood (thrombocytopenia) - which can cause bruising and bleeding, a reduction in the number of several types of blood cells at the same time (pancytopenia)
- Effects on the nervous system: headache, difficulty sleeping (insomnia), strange tastes (dysgeusia), becoming less sensitive to touch (hypoesthesia), prickly or tingling skin (paraesthesia), loss of feeling in the hands or feet (peripheral neuropathy), dizziness, fits (convulsions)
- Effects in the eye: eye pain, swelling within the eye (oedema), separation of the inner lining of the eye (detached retina), seeing floaters
- Effects in the ear: earache
- Effects on breathing: coughing
- Effects on the stomach and digestion: feeling and being sick, stomachache, constipation, wind, indigestion (dyspepsia), difficulty swallowing (dysphagia)
- Effects on the skin: inflamed skin (dermatitis), itching (pruritis), sweating at night
- Effects on the muscles, joints or bones: back pain, pain in the muscles (myalgia) or joints (arthralgia), stiff muscles (rigor), muscle cramps
- Infections: fungal infection in the mouth (oral candidiasis), infections caused by bacteria or viruses in the blood, inflammation of cellular tissue (cellulitis), inflammation or infection of the kidneys or bladder
- Effects in the liver: a rise in some liver enzymes, which will only be seen during blood tests
- Effects in the kidney: changes to the normal working of the kidneys
- Effects on eating: loss of appetite (anorexia), weight loss
- General effects: tiredness, fever, pain, chest pain, loss of energy (asthenia), generally feeling unwell (malaise)
- Effects on mood or behaviour: depression, feeling anxious, confused, having unusual thoughts

Uncommon (may affect up to 1 in 100 people):

- Effects in the heart: changes to the normal heart beat (arrhythmia)
- Effects on circulation: low blood pressure (hypotension), which can cause you to feel light headed or faint
- Effects on the blood: a decrease in the production of blood cells in the bone marrow
- Effects in the nerves: shaking or trembling (tremor)
- Effects in the eyes: red, swollen eyes (conjunctivitis), abnormal vision
- Effects in the ears: deafness
- Effects on the stomach or digestion: swollen stomach, mouth ulcers, inflammation of the pancreas (pancreatitis) where you may notice severe pain in the stomach and back
- Effects on the skin: hair loss (alopecia), itchy rash or swellings (urticaria), dry skin
- Effects in the kidneys: blood in the urine (haematuria), kidney failure
- Effects in the liver: a rise in the liver enzyme called alanine aminotransferase (which will only be seen during blood tests)
- Effects on fertility: infertility in men
- Effects on mood or behaviour: having unusual changes in mood and behaviour, losing contact with reality such as hearing voices or seeing things that are not there, feeling agitated

Rare (may affect up to 1 in 1000 people):

- Effects on the blood: failure of the production of all types of blood cells (red blood cells, white blood cells and platelets) in the bone marrow

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, pharmacist or nurse. 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 Rowex

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

Shelf life for bottles:

After first opening: 2 months

Do not use this medicine after the expiry date which is stated on the label, 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.

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 Valganciclovir Rowex contains

- The active substance is valganciclovir. Each tablet contains 496.3 mg of valganciclovir hydrochloride equivalent to 450 mg of valganciclovir (as free base).
- The other ingredients are:
Tablet core:
Cellulose microcrystalline (PH101),
Crospovidone (Type A), Povidone (K-30),
Stearic acid 50

Film-coating: Opadry Pink 15B24005:
Hypromellose (3 cP), Hypromellose (6 cP),
Titanium dioxide (E171), Macrogol 400,
Iron oxide red (E172), Polysorbate 80

What Valganciclovir Rowex looks like and contents of the pack

Valganciclovir Rowex are pink, oval, biconvex, film coated tablets (16.7 x 7.8 mm), debossed with "J" on one side and "156" embossed on the other side.

Aluminium/PVC/Aluminium/OPA blister: 10, 30, 60, 90, 120 film-coated tablets.

HDPE container with [child resistant] polypropylene screw caps: 60 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers:

LEK S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, Sachsen-Anhalt, 39179 Barleben, Germany.
Lek Pharmaceuticals d.d., Verovškova ulica 57, 1526 Ljubljana, Slovenia.

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

The Netherlands	Valganciclovir Sandoz 450 mg, filmomhulde tabletten
Austria	Valganciclovir Sandoz 450 mg - Filmtabletten
Belgium	Valganciclovir Sandoz 450 mg filmomhulde tabletten
Croatia	Nyctos 450 mg filmom obložene tablete
Cyprus	Valganciclovir HCL Sandoz 450 mg
Czech Republic	Valganciclovir Sandoz 450 mg potahované tablety
Denmark	Valganciclovir Sandoz
Estonia	Valganciclovir Sandoz
Finland	Valganciclovir Sandoz
France	VALGANCICLOVIR SANDOZ 450 mg, comprimé pelliculé
Germany	Valganciclovir HEXAL 450 mg Filmtabletten
Greece	Valganciclovir /Sandoz
Ireland	Valganciclovir Rowex 450 mg Film-coated tablets
Italy	VALGANCICLOVIR SANDOZ
Latvia	Valganciclovir Sandoz 450 mg apvalkotās tabletes
Lithuania	Valganciclovir Sandoz 450 mg plėvele dengtos tabletės
Luxembourg	Valganciclovir Sandoz 450 mg comprimés pelliculés
Norway	Valganciclovir Sandoz
Poland	Ceglar
Portugal	Valganciclovir Sandoz
Romania	VALGANCICLOVIR SANDOZ 450 mg comprimate filmate
Slovenia	Valganciklovir Lek 450 mg filmsko obložene tablete
Spain	Valganciclovir Sandoz 450 mg comprimidos recubiertos con película EFG
Sweden	Valganciclovir Sandoz
the United Kingdom	Valganciclovir 450mg Film-coated Tablets

This leaflet was last revised in 11/2014.

Internal code
Article No

Artwork Checklist	Job Description	Version Number	Size	Inks						ACCF
	Valganciclovir Rowex 450 mg PIL	2	165 x 620							
	Market	Proof Date	Cutter Ref.	Colour						
	IM	12/11/2014	N/A	Front	✓					
				Back	✓					