

Package leaflet: Information for the patient

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

1. What <Invented name> is and what it is used for

<Invented name> contains the active substance valganciclovir (as valganciclovir hydrochloride). <Invented 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.

<Invented 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 <Invented name>

Do not take <Invented name>:

- 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 <Invented name>:

- if you are allergic to aciclovir, penciclovir, valaciclovir or famciclovir, which are medicines used to treat other virus infections.
- 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 <Invented name> and more tests will be done while you are taking the tablets
- if you are having radiotherapy or blood dialysis

- 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 <Invented name>, or if your doctor changes your dose during the treatment. 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 <Invented name>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you take other medicines at the same time as taking <Invented name> the combination could affect the amount of medicine in 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 it with <Invented name> can cause convulsions (fits).
- zidovudine, didanosine, stavudine, tenofovir or similar kinds of medicines used to treat AIDS.
- adefovir (used to treat Hepatitis B).
- probenecid (a medicine used to treat gout). Taking probenecid and <Invented 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, hydroxyurea or similar kinds of medicines to treat cancer.
- trimethoprim, trimethoprim/sulpha combinations and dapsone (antibiotics).
- pentamidine (medicine to treat parasite or lung infections).
- flucytosine or amphotericin B (anti-fungal agents).

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

You should not take <Invented name> if you are pregnant unless your doctor recommends it. Taking <Invented name> when you are pregnant could harm your unborn baby.

Breast-feeding

Do not take <Invented name> if you are breast-feeding. If your doctor wants you to begin treatment with <Invented name> you must stop breast-feeding before you start to take this medicine.

Women of child-bearing age must use effective contraception when taking <Invented name> and for at least 30 days after treatment has finished.

Men whose partners could become pregnant should use condoms while taking <Invented name> 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 sleepy, dizzy, tired, shaky or confused while taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

3. How to take <Invented 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. 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.

Do not take more tablets than prescribed by your doctor to avoid overdose.

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 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 <Invented 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 people

<Invented 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

<Invented name> 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 kidney function. Your child should continue with this dose for up to 100 days following their transplant. If your child has received a kidney transplant, your doctor may advise to take the dose for 200 days.

Method of administration

- <Invented name> should, whenever possible, be taken with food. If you are unable to eat for any reason, you should still take your dose of <Invented name> as usual.
- Swallow the tablet whole. Do not crush or break the tablets.
- For children who can't swallow valganciclovir film-coated tablets, other formulations may be available. Ask your pharmacist.

If you take more <Invented 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, liver or kidneys. Other side effects may include stomach pain, being sick, diarrhoea, fits and shaking. You may need hospital treatment.

If you forget to take <Invented 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 a forgotten tablet.

If you stop taking <Invented name>

Do 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.

Stop taking <Invented name> and contact your doctor or go to your nearest hospital emergency department immediately if you think you may have any of the following side effects:

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

- low white blood cell counts - you may notice frequent infections, such as fever, chills, sore throat or mouth ulcers.
- 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):

- 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.
- a reduction in the number of red and white blood cells, as well as platelets (pancytopenia).
- inflammation of the pancreas (pancreatitis): where you may notice severe upper stomach pain and back, often with nausea and vomiting.
- fits (convulsions).
- infections caused by bacteria or viruses in the blood (sepsis) – which may cause high fever, chills, headache, confusion and rapid breathing.
- swelling within the eye (macular oedema),
- retinal detachment (a detached retina is when the thin layer at the back of your eye (retina) becomes loose).

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

- failure of the bone marrow to produce blood cells.
- seeing, hearing or feeling things that are not (hallucinations).
- having abnormal thoughts or feelings, losing contact with reality.
- failure of kidney function.

Rare (may affect up to 1 in every 1,000 people)

- severe allergic reaction (anaphylactic shock). You may experience:
 - 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.

These are serious side effects. You may need medical attention.

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

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

- thrush and oral thrush (including oral candidiasis).

- upper respiratory tract infection (e.g. sinusitis, tonsillitis).
- loss of appetite.
- headache.
- coughing.
- feeling short of breath or having trouble breathing (dyspnoea).
- diarrhoea.
- feeling and being sick.
- stomach ache (abdominal pain).
- eczema (inflammation of the skin).
- tiredness.
- fever.

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

- flu (influenza).
- inflammation of the skin and the tissues under the skin (cellulitis).
- inflammation or infection of the kidneys or bladder (which may include signs such as pain or discomfort when urinating, blood in urine, pain in your abdomen, back pain, needing to urinate more often during the day or night).
- mild allergic reaction – the signs may include red, itchy skin.
- weight loss.
- feeling depressed, anxious or confused.
- difficulty sleeping (insomnia).
- Change to the way things taste (dysgeusia).
- becoming less sensitive to touch (hypoesthesia).
- prickly or tingling skin (paraesthesia).
- loss of feeling in the hands or feet (peripheral neuropathy).
- dizziness.
- eye inflammation (conjunctivitis), eye pain or sight problems.
- dots and lines (floaters) or flashes of light in the eyes
- ear pain.
- low blood pressure (hypotension), which can cause you to feel light headed or faint.
- difficulty swallowing (dysphagia).
- constipation, wind, indigestion (dyspepsia), swollen stomach.
- mouth ulcers.
- abnormal results of the liver and kidney laboratory tests.
- night sweats.
- rash, itching (pruritus),
- hair loss (alopecia)
- back pain, pain in the muscles (myalgia) or joints (arthralgia), muscle cramps.
- your kidneys may not work as well and your blood creatinine (a waste product) levels may be higher as a result.
- chills, pain, unusual weakness (asthenia), generally feeling unwell (malaise).

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

- changes to the normal heart beat (arrhythmia).
- feeling agitated.
- shaking or trembling (tremor).
- deafness.
- dry skin.
- hives (urticaria).
- blood in urine.
- infertility in men.
- chest pain.

Separation of the inner lining of the eye (detached retina) has only happened in AIDS patients treated with valganciclovir (the active substance of this medicine) for CMV infection.

Side effects in children and adolescents

The side effects reported in children and adolescents are similar to the side effects reported for adults but with, in some cases, increased frequencies.

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 [To be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented 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 label and carton after 'EXP'. The expiry date refers to the last day of that month.

After opening, use within 3 months.

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 <Invented name> contains

- The active substance is valganciclovir. Each tablet contains 450 mg valganciclovir (as valganciclovir hydrochloride).
- The other ingredients are cellulose, microcrystalline (E460), crospovidone, stearic acid (E570), hypromellose (E464), titanium dioxide (E171), macrogol, iron oxide red (E172) and polysorbate (E433).

What <Invented name> looks like and contents of the pack

<Invented name> are pink film-coated, oval, biconvex, bevelled edge tablets marked with "M" on one side of the tablet and "V45" on the other side, with dimensions 18.4 mm x 8.4 mm.

<Invented name> is packed in HDPE bottles with a child resistant cap containing 60 film-coated tablets, in blister packs of 60 film-coated tablets, or in perforated unit dose blister packs of 60 x 1 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Mylan Hungary Kft.
H-2900 Komárom
Mylan utca 1.

Hungary

Generics [UK] Limited
Station Close
Potters Bar
Hertfordshire
EN6 1TL
United Kingdom

Mylan Germany GmbH
Zweigniederlassung Bad Homburg v. d. Hoehe
Benzstrasse 1, 61352 Bad Homburg v. d. Hoehe,
Hessen,
Germany

Mylan UK Healthcare Limited
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Station Close
Potters Bar
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United Kingdom

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

[To be completed nationally]

This leaflet was last revised in
[To be completed nationally]