

Valganciclovir Sandoz

valganciclovir hydrochloride tablet

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Valganciclovir Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine.

WHAT IS USED FOR

This medicine is used to treat:

- CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS)
- Prophylaxis of CMV infection and disease following solid organ transplantation in patients at risk of CMV disease.

It contains the active ingredient valganciclovir hydrochloride. Valganciclovir belongs to a group of medicines used to prevent the growth of viruses.

It works by acting against a virus called cytomegalovirus or CMV (a type of herpes virus). It prevents this virus from growing and multiplying in the body. In people with poor immunity, CMV can cause infections. Poor immunity can be caused by: HIV/AIDS or by medicines taken after an organ transplant.

Valganciclovir is also used to:

- CMV eye infections in AIDS patients, which if left untreated may cause blindness. It is not a cure for CMV eye infections
- Prevent CMV infection in patients following organ transplantation.

Valganciclovir Sandoz is not effective against any underlying HIV infection

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

BEFORE YOU TAKE VALGANCICLOVIR SANDOZ

Animal and other laboratory studies have shown Valganciclovir causes infertility, birth defects and cancer. It is possible that these effects may also occur in humans.

When you must not take it

Do not take this medicine if you have an allergy to:

- valganciclovir hydrochloride, the active ingredient(s), or to any of the other ingredient(s) listed at the end of this leaflet under Product Description
- Ganciclovir, valaciclovir or aciclovir or any other similar medicines
- If you have very low blood counts for platelets (which help clotting),

neutrophils (a type of white blood cell which defends against infection) or low haemoglobin (oxygen carrying substance in the blood).

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Use in children

There is limited information on the safety and effectiveness of the use of Valganciclovir in children. Your doctor will advise you whether Valganciclovir is suitable for your child.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes. Especially any medicine which you have taken previously to treat your current condition.

Tell your doctor if you have or have had any of the following medical conditions:

- history of low blood counts for platelets (thrombocytopenia), neutrophils (neutropenia) or anaemia
- you have or previously have had poor kidney function

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding. Valganciclovir Sandoz is not recommended for use during pregnancy. It may affect your developing baby if you take it during pregnancy. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast feeding or intend to breast feed. It is not known whether Valganciclovir Sandoz passes into breast milk. Breast feeding is not recommended during treatment with Valganciclovir Sandoz.

You are a woman who could become pregnant and you are not using contraception.

You must use a reliable form of contraception during Valganciclovir therapy, and for at least 30 days after stopping Valganciclovir, unless you are not sexually active. You are a sexually active man.

You should use condoms during and for at least 90 days following treatment with Valganciclovir unless it is certain that your female partner is not at risk of pregnancy.

Information is limited on the safety and effectiveness of Valganciclovir Sandoz in children. Your doctor will advise.

If you have not told your doctor about any of the above, tell him/her before you start taking Valganciclovir Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Valganciclovir Sandoz may interfere with other medicines.

These include:

- medicines used to treat gout such as probenecid
- medicines used to treat HIV infection, such as zidovudine (AZT) and didanosine(ddI)
- a combination of medicines used to treat some infections, such as imipenem/cilastatin
- medicine used to prevent organ rejection after a transplant such as mycophenolate mofetil, ciclosporin,
- medicines for the treatment of cancer such as vincristine, adriamycin and hydroxyurea
- anti-infective medications such as dapsone, pentamidine, flucytosine and amphotericin B
- other medications for the treatment of HIV or HIV related infections such as nucleoside analogues
- (lamivudine, also known as 3TC; stavudine, also known as D4T; zalcitabine also known as ddc; abacavir; lamivudine / zidovudine or; abacavir / lamivudine / zidovudine combinations).

These medicines may be affected by Valganciclovir Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist will have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE VALGANCICLOVIR SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Valganciclovir Sandoz needs to be taken exactly as prescribed.

Your doctor will tell you how many Valganciclovir Sandoz tablets to take each day.

For Treatment of CMV Retinitis in AIDS

- **Induction Treatment (for active CMV retinitis)**
The usual dose is 900mg (two 450mg tablets) twice daily with food for 21 days
- **Maintenance Treatment (after induction treatment or for inactive CMV retinitis)**
The usual dose is 900mg (two 450mg tablets) once daily with food.

Prevention of CMV Disease in Transplantation

The usual dose is 900mg (two 450mg tablets) once daily with food, starting within 10 days of your organ transplant until 100 days after the transplant.

If you have received a kidney transplant, the same daily dose is required until 200 days after the transplant. Your dose may have to be reduced or stopped if you have or develop low blood counts, have kidney disease or if you are older than 65 years.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Valganciclovir Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water. Tablets must be taken with food.

When to take Valganciclovir Sandoz

Take your medicine at about the same time each day. Take during or immediately after a meal. If you take it on an empty stomach, it may not work as well.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take Valganciclovir Sandoz

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

Continue taking your medicine until your doctor tells you to stop.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Valganciclovir Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE TAKING VALGANCICLOVIR SANDOZ

Things you must do

If you are about to be started on any new medicine, remind your doctor and

pharmacist that you are taking VALGANCICLOVIR SANDOZ.

A barrier contraceptive should be used while taking VALGANCICLOVIR SANDOZ and for 90 days after stopping treatment. Tell your doctor if you become pregnant while taking VALGANCICLOVIR SANDOZ.

Condoms should be used by sexually active men while taking Valganciclovir and for 90 days after stopping treatment.

Women who are of childbearing potential should use contraception during and for at least 30 days after stopping Valganciclovir.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Your doctor may do some tests (blood cell counts) from time to time to make sure the medicine is working and to prevent unwanted side effects. If blood cell counts are low then this may reduce your ability to fight infection or for your blood to clot efficiently. If left undetected these effects on blood cells may contribute to death of serious illness.

If you have a CMV eye infection, you must also see your doctor regularly to monitor the condition of your retina (part of the eye). If you have not taken your medicine exactly as prescribed, you must tell your doctor. Otherwise, your doctor may think it was not effective and change your treatment unnecessarily.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Valganciclovir Sandoz to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine without checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays. Do not break or crush the tablets.

Things to be careful of

Be careful driving or operating machinery until you know how Valganciclovir Sandoz affects you.

This medicine may cause dizziness, confusion, seizures, drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Valganciclovir Sandoz.

Valganciclovir helps most people with CMV infections but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Dizziness
- Looking pale
- Diarrhoea
- Nausea
- Fever
- Vomiting
- Headache

These are mild side effects of the medicine and are short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- skin rash
- abdominal pain
- cough
- fatigue (tiredness)
- oral thrush (sore, creamy yellow raised patches in the mouth)
- insomnia (inability to sleep)
- worsening of your eyesight

The above list includes serious side effects that may require medical attention. Serious side effects are rare

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the tongue, lips or throat
- any sign of infection such as fever, chills, sore throat or mouth ulcers
- unexplained bruising or bleeding
- thinking, hearing or seeing things that are not real
- confusion
- agitation
- fits

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER TAKING VALGANCICLOVIR SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Valganciclovir Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Valganciclovir Sandoz 450mg - pink, convex oral tablets with 'J' on one side and '156' on the other side.

Available in blisters of 60 tablets

Ingredients

Active ingredients:

- Each Valganciclovir Sandoz tablet contains 450mg of valganciclovir (as hydrochloride).

Inactive ingredients:

- microcrystalline cellulose
- crospovidone
- stearic acid
- povidone
- hypromellose
- titanium dioxide
- macrogol 400
- iron oxide red
- polysorbate 80

This medicine does not contain lactose, sucrose, gluten and tartrazine,

Supplier

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