

VALGANCICLOVIR AN

Tablets

Pronounced val gan SYE kloh veer

contains the active ingredient valganciclovir hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VALGANCICLOVIR AN tablets.

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 VALGANCICLOVIR AN 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.

You may need to read it again.

What VALGANCICLOVIR AN is used for

VALGANCICLOVIR AN contains the active ingredient valganciclovir. In the body valganciclovir rapidly changes to ganciclovir.

VALGANCICLOVIR AN belongs to a class of medicines used to prevent the growth of viruses.

VALGANCICLOVIR AN acts against a virus called cytomegalovirus or CMV (a type of herpes virus). It prevents this virus

from growing and multiplying in the body. CMV causes infections, mainly in people with poor immunity. Poor immunity can be caused by HIV/AIDS or by medications taken after an organ transplant.

VALGANCICLOVIR AN is used to treat CMV eye infections (known as CMV retinitis) in AIDS patients, which, if left untreated can cause blindness. It is not a cure for CMV eye infections.

VALGANCICLOVIR AN is not effective against any underlying HIV infection.

VALGANCICLOVIR AN is also used to prevent CMV infection in patients following organ transplantation.

Your doctor, however, may have prescribed VALGANCICLOVIR AN for another purpose.

Ask your doctor if you have any questions about why VALGANCICLOVIR AN has been prescribed for you.

VALGANCICLOVIR AN is not addictive.

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

Before you take VALGANCICLOVIR AN

Animal and other laboratory studies have shown VALGANCICLOVIR AN 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 VALGANCICLOVIR AN if

- 1. you have had an allergic reaction to VALGANCICLOVIR AN, ganciclovir, valaciclovir or aciclovir or any ingredients listed at the end of this leaflet**
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
- 2. 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)**
- 3. the package is torn or shows signs of tampering**
- 4. the expiry date (EXP) printed on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking VALGANCICLOVIR AN, talk to your doctor.

Use in children

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

Before you start to take it

Tell your doctor if

- 1. you are allergic to any other medicines, foods, dyes or preservatives.**
Especially any medicine which you have taken previously to treat your current condition
- 2. you have any other health problems, especially the following:**
 - you have a history of low blood counts for platelets (thrombocytopenia), neutrophils (neutropenia) or anaemia
 - you have, or previously have had, poor kidney function
- 3. you are pregnant or intend to become pregnant**
VALGANCICLOVIR AN is not recommended for use during pregnancy.
VALGANCICLOVIR AN may affect your developing baby if you take it during pregnancy. Your doctor will discuss the risks and benefits of using VALGANCICLOVIR AN if you are pregnant.
- 4. you are breast-feeding or intend to breast-feed**
It is not known whether VALGANCICLOVIR AN passes into breast milk. Breast-feeding is not recommended during therapy with VALGANCICLOVIR AN.

If you have not told your doctor about any of the above, tell them

before you start taking VALGANCICLOVIR AN.

Taking other medicines

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

Some medicines may interfere with VALGANCICLOVIR AN. These medicines include:

- probenecid, a medicine used to treat gout
- zidovudine (AZT) a medicine, used to treat HIV infection
- imipenem/cilastatin combination of medicines used to treat some infections
- didanosine (ddI), a medicine used to treat HIV infection
- mycophenolate mofetil, a medicine used to prevent organ rejection after a transplant
- medicines for the treatment of cancer such as vincristine, adriamycin, hydroxyurea
- anti-infective agents such as dapsone, pentamidine, flucytosine, pegylated interferons plus ribavirin and amphotericin B
- other medicines 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 AN, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking VALGANCICLOVIR AN.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take VALGANCICLOVIR AN

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

They may differ from the information contained in this leaflet.

How much to take

Take VALGANCICLOVIR AN exactly as your doctor has prescribed.

Your doctor will tell you how many VALGANCICLOVIR AN tablets to take each day.

Treatment of CMV Retinitis in AIDS for adults

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

Prevention of CMV Disease in Transplantation for adults

The usual dose is 900 mg (two 450 mg 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.

Prevention of CMV Disease in Transplantation for children
Your doctor will let you know how many VALGANCICLOVIR AN tablets you should give your child each day.

How to take it

Swallow tablets whole with a glass of water. VALGANCICLOVIR AN must be taken with food.

When to take it

Take VALGANCICLOVIR AN during or immediately after a meal.

If you take VALGANCICLOVIR AN on an empty stomach, it may not work as well.

Take VALGANCICLOVIR AN at about the same time each day.

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

How long to take it

Continue taking VALGANCICLOVIR AN until your doctor tells you to stop.

If you forget to take it

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

Otherwise, take it as soon as you remember and then go back to taking it as you would normally.

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

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

If you have trouble remembering your dose, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons

Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much VALGANCICLOVIR AN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

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

While you are taking VALGANCICLOVIR AN

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking VALGANCICLOVIR AN.

A barrier contraceptive should be used while taking VALGANCICLOVIR AN and for 90 days after stopping treatment.

Tell your doctor if you become pregnant while taking VALGANCICLOVIR AN.

See your doctor regularly so that your CMV disease, blood cell counts and any other potential side effects may be monitored carefully.

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 or 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).

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Things you must not do

Do not stop taking VALGANCICLOVIR AN or change the dose without first checking with your doctor.

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

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Do not give VALGANCICLOVIR AN to anyone else even if they have the same condition as you.

Be careful when handling VALGANCICLOVIR AN tablets. Do not break or crush them. If you accidentally touch broken or crushed tablets, wash your hands thoroughly with soap and water. If any powder from the tablet gets in your eyes, rinse your eyes thoroughly with water.

Things to be careful of

Be careful driving or operating machinery until you know how VALGANCICLOVIR AN affects you.

VALGANCICLOVIR AN may cause drowsiness, dizziness, confusion or seizures (fits) in some people and therefore may affect alertness. Make sure you know how you react to VALGANCICLOVIR AN before you drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Side effects

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

VALGANCICLOVIR AN 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. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- dizziness
- looking pale
- diarrhoea
- nausea
- fever
- vomiting
- headache

These are more common side effects of VALGANCICLOVIR AN and are usually short-lived.

Tell your doctor immediately 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

These side effects may be serious. You may require medical attention.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- 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

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

After taking VALGANCICLOVIR AN

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep VALGANCICLOVIR AN in a cool dry place where the temperature stays below 25°C.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep VALGANCICLOVIR AN where young 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 VALGANCICLOVIR AN, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

Availability

VALGANCICLOVIR AN comes in 450 mg film-coated tablets.

VALGANCICLOVIR AN comes in bottles containing 60 tablets.

What VALGANCICLOVIR AN looks like

VALGANCICLOVIR AN 450 mg tablets are pink convex oval tablets plain on one side and "450" on the other side.

Ingredients

Active ingredient - valganciclovir

- each VALGANCICLOVIR AN tablet contains 450 mg of valganciclovir

Inactive ingredients -

VALGANCICLOVIR AN film-coated tablets also contain

- microcrystalline cellulose (460)
- povidone K-30
- crospovidone
- stearic acid (570)
- hypromellose
- titanium dioxide (171)
- macrogol 400
- polysorbate 80 (433)
- FD&C red.

VALGANCICLOVIR AN tablets are lactose and gluten free.

Sponsor

Juno Pharmaceuticals Pty Ltd
Level 2, 6 Bond St
South Yarra VIC 3141
AUSTRALIA

Australian Registration Number
AUST R 262931

This leaflet was prepared in
December 2017