

VALGANCICLOVIR VIATRIS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking VALGANCICLOVIR VIATRIS?

VALGANCICLOVIR VIATRIS contains the active ingredient valganciclovir. VALGANCICLOVIR VIATRIS acts against a virus called cytomegalovirus or CMV. VALGANCICLOVIR VIATRIS is used to treat CMV eye infections in AIDS patients and to prevent CMV infection in patients following organ transplantation.

For more information, see Section [1. Why am I taking VALGANCICLOVIR VIATRIS?](#) in the full CMI.

2. What should I know before I take VALGANCICLOVIR VIATRIS?

Do not take if you have ever had an allergic reaction to valganciclovir or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take VALGANCICLOVIR VIATRIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VALGANCICLOVIR VIATRIS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take VALGANCICLOVIR VIATRIS?

- Induction treatment for adults (for active CMV retinitis): 900 mg twice daily with food for 21 days. Take two 450 mg tablets in the morning and two 450 mg tablets in the evening with food.
- Maintenance treatment for adults (after induction treatment or for inactive CMV retinitis): 900mg once daily with food. Take two 450 mg tablets at the same time each day with food.
- Prevention of CMV disease in transplantation for adults: 900 mg once daily with food, starting 10 days post transplantation until 100 days post transplantation. If you have received a kidney transplant, the same daily dose is required until 200 days post transplantation. Take two 450 mg tablets once at the same time each day with food.
- Prevention of CMV disease in transplantation for children: Your doctor will advise the appropriate dose.

More instructions can be found in Section [4. How do I take VALGANCICLOVIR VIATRIS?](#) in the full CMI.

5. What should I know while taking VALGANCICLOVIR VIATRIS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking VALGANCICLOVIR VIATRIS.• Tell your doctor if you become pregnant while taking VALGANCICLOVIR VIATRIS.• See your doctor regularly so that your CMV disease and blood cell counts can be monitored.• If you have CMV eye infection, see your doctor regularly to monitor your retina (part of your eye).
Things you should not do	<ul style="list-style-type: none">• Do not stop taking VALGANCICLOVIR VIATRIS or change the dose without checking with your doctor.• Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how VALGANCICLOVIR VIATRIS affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep VALGANCICLOVIR VIATRIS in a cool dry place where the temperature stays below 25°C.• Keep medicine in the bottle until it is time to take them.

For more information, see Section [5. What should I know while taking VALGANCICLOVIR VIATRIS?](#) in the full CMI.

6. Are there any side effects?

Go to your nearest hospital if you experience: swelling of the tongue, lips or throat, any sign of infection such as fever, chills sore throat or mouth ulcers, unexplained bruising or bleeding, hallucinations, confusion, agitation; or fits.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

VALGANCICLOVIR VIATRIS

Active ingredient(s): valganciclovir

Consumer Medicine Information (CMI)

This leaflet provides important information about taking VALGANCICLOVIR VIATRIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking VALGANCICLOVIR VIATRIS.**

Where to find information in this leaflet:

- [1. Why am I taking VALGANCICLOVIR VIATRIS?](#)
- [2. What should I know before I take VALGANCICLOVIR VIATRIS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take VALGANCICLOVIR VIATRIS?](#)
- [5. What should I know while taking VALGANCICLOVIR VIATRIS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking VALGANCICLOVIR VIATRIS?

VALGANCICLOVIR VIATRIS contains the active ingredient valganciclovir.

In the body valganciclovir rapidly changes to ganciclovir.

VALGANCICLOVIR VIATRIS belongs to a group of medicines used to prevent the growth of viruses.

VALGANCICLOVIR VIATRIS 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 VIATRIS 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 VIATRIS is not effective against any underlying HIV infection.

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

VALGANCICLOVIR VIATRIS is not addictive.

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

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

2. What should I know before I take VALGANCICLOVIR VIATRIS?

Animal and other laboratory studies have shown VALGANCICLOVIR VIATRIS causes infertility, birth defects

and cancer. It is also possible that these effects may occur in humans.

Warnings

Do not take VALGANCICLOVIR VIATRIS if:

- you are allergic to valganciclovir, ganciclovir, valaciclovir, aciclovir, famciclovir or penciclovir. These medicines come from the same class as VALGANCICLOVIR VIATRIS and allergic reactions may occur. Or any of the 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

Always check the ingredients to make sure you can take this medicine.

- 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).

Use in children

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

Check with your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives, especially any medicine which you have taken previously to treat your current condition.
- 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.

are pregnant or intend to become pregnant

- VALGANCICLOVIR VIATRIS is not recommended for use during pregnancy. VALGANCICLOVIR VIATRIS may affect your developing baby if you take it during pregnancy.
- your doctor will discuss the risks and benefits of using VALGANCICLOVIR VIATRIS if you are pregnant.

are breast-feeding or intend to breast-feed

- It is not known whether VALGANCICLOVIR VIATRIS passes into breast milk. Breast-feeding is not recommended during therapy with VALGANCICLOVIR VIATRIS.

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

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

are a sexually active man

- you should use condoms during and for at least 90 days following treatment with VALGANCICLOVIR VIATRIS unless it is certain your female partner is not at risk of pregnancy.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Make sure your doctor is aware that you are pregnant or plan to become pregnant or are breastfeeding or intend to breastfeed. You must use a reliable form of contraception during VALGANCICLOVIR VIATRIS therapy, and for at least 30 days after stopping VALGANCICLOVIR VIATRIS, unless you are not sexually active.

3. What if I am taking other medicines?

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

Some medicines and VALGANCICLOVIR VIATRIS may interfere with each other. These include:

- imipenem/cilastatin (Primaxin®), a combination of medicines used to treat some infections
- probenecid (e.g. Benemid®), a medicine used to treat gout
- zidovudine (AZT, Retrovir®, Combivir®), didanosine (ddl or Videx®), stavudine, or other medicines used to treat HIV infection
- medicines for the treatment of cancer such as doxorubicin, vinblastine, vincristine, hydroxyurea, adriamycin
- mycophenolate mofetil (CellCept®), and other medicines used to prevent organ rejection after a transplant e.g. ciclosporin, tacrolimus
- anti-infective agents such as trimpethroprim / sulphonamides, dapsone, pentamide, flucytosine pegylated interferons plus ribavirin and amphotericin B

These medicines may be affected by VALGANCICLOVIR VIATRIS, or may affect how well it works. You may need to

take different amounts of your medicine, or you may need to take different medicines.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VALGANCICLOVIR VIATRIS.

4. How do I take VALGANCICLOVIR VIATRIS?

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 on the bottle, ask your doctor or pharmacist for help.

How much to take

Take VALGANCICLOVIR VIATRIS exactly as your doctor has prescribed.

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

Treatment of CMV Retinitis in AIDS (adult patients)

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

Take two 450 mg tablets once at the same time each day 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 with 10 days post transplantation until 100 days post transplantation.

If you have received a kidney transplant, the same daily dose is required until 200 days post transplantation.

Take two 450 mg tablets once at the same time each day with food.

Your dose may have been 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 VIATRIS tablets you should give your child each day.

How to take it

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

When to take VALGANCICLOVIR VIATRIS

- **Take VALGANCICLOVIR VIATRIS during or immediately after a meal.**

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

- Take VALGANCICLOVIR VIATRIS at about the same time each day for as long as your doctor tells you to.

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

How long to take it for

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

If you forget to take VALGANCICLOVIR VIATRIS

VALGANCICLOVIR VIATRIS should be taken regularly at the same time each day.

If you miss your dose at the usual time and 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 VALGANCICLOVIR VIATRIS

If you think that you or anyone else have taken too much VALGANCICLOVIR VIATRIS, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking VALGANCICLOVIR VIATRIS?

Things you should do

- Tell any other doctors, dentists and pharmacists who treat you that you are taking VALGANCICLOVIR VIATRIS.
- **Call your doctor straight away if you become pregnant while taking VALGANCICLOVIR VIATRIS.**

Condoms should be used by sexually active men while taking VALGANCICLOVIR VIATRIS 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 VIATRIS.

- 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 is not effective and change your treatment unnecessarily.
- Keep all of your appointments with your doctor so that your progress can be checked.

Things you should not do

- Do not take VALGANCICLOVIR VIATRIS to treat any other complaints unless your doctor tells you to.
- Do not give VALGANCICLOVIR VIATRIS to anyone else even if they have the same condition as you.
- Do not stop taking VALGANCICLOVIR VIATRIS or change the dosage 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 take VALGANCICLOVIR VIATRIS after the expiry date (EXP) printed on the pack has passed or if the packaging is torn or shows signs of tampering.
- Be careful when handling the VALGANCICLOVIR VIATRIS tablets. Do not break or crush them. Do not get broken or crushed tablets on your skin or in your eyes. If you accidentally touch broken or crushed tablets, wash your hands thoroughly with soap and water. If any of the powder from the tablets gets in your eyes, rinse your eyes thoroughly with water.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how VALGANCICLOVIR VIATRIS affects you.

VALGANCICLOVIR VIATRIS may cause drowsiness, dizziness, confusion or seizures (fits) in some people and therefore may affect alertness. If you have any of these symptoms, do not drive or operate machinery or do anything else that could be dangerous.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat or dampness can destroy some medicines.

Keep it 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.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • diarrhoea • vomiting • nausea • dizziness • headache • insomnia (inability to sleep) • looking pale • fever 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • skin rash • abdominal pain • cough • fatigue (tiredness) • oral thrush (sore, creamy yellow raised patches in the mouth) • worsening of your eyesight • swelling of the tongue, lips or throat 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • any signs 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 	<p>these serious side effects.</p>

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

Other side effects not listed here may occur in some people.

If you are over 65 years of age you may have an increased chance of getting side effects.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What VALGANCICLOVIR VIATRIS contains

Active ingredient (main ingredient)	valganciclovir 450 mg per tablet
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • crospovidone • stearic acid • microcrystalline cellulose • OPADRY complete film coating system 15B565009 BROWN (ARTG PI No.: 109242)
Potential allergens	trace amount of sulfites.

Do not take this medicine if you are allergic to any of these ingredients.

What VALGANCICLOVIR VIATRIS looks like

VALGANCICLOVIR VIATRIS are pink, film-coated, oval, biconvex, beveled edge tablets debossed with M on one side of the tablet and V45 on the other side. (AUST R 218477).

Available in bottle of 60 tablets.

Who distributes VALGANCICLOVIR VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

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