

# VALACICLOVIR GENERICHEALTH

## TREATMENT FOR CYTOMEGALOVIRUS

(*valaciclovir hydrochloride monohydrate*) film-coated tablet

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### Consumer Medicine Information

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#### What is in this leaflet

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This leaflet answers some common questions about Valaciclovir generichealth.

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

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

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

Keep this leaflet with your medicine. You may need to read it again.

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#### What Valaciclovir generichealth is used for

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Valaciclovir generichealth is used to prevent cytomegalovirus (CMV) infection and disease following solid organ transplantation.

Valaciclovir generichealth belongs to a group of medicines called antivirals. It works by stopping the production of CMV, preventing infection. Valaciclovir generichealth also prevents herpes simplex infections.

CMV is another type of herpes virus. It can cause symptoms similar to glandular fever (high temperature, sore throat and swollen glands).

Your doctor may have prescribed Valaciclovir generichealth for another reason. Ask your doctor if you have any questions about why Valaciclovir generichealth has been prescribed for you.

Valaciclovir generichealth is not recommended for use in children, as there have been no studies of its effects in children.

Valaciclovir generichealth is available only with a doctor's prescription.

There is no evidence that Valaciclovir generichealth is addictive.

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#### Before you take Valaciclovir generichealth

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*When you must not take it*

**Do not take Valaciclovir generichealth if you are allergic to:**

- **medicines containing valaciclovir, aciclovir;**
- **any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include skin rash, itching or hives (lumpy rash), swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath or fainting.

**Do not take Valaciclovir generichealth if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.**

**Your doctor will discuss the risks and benefits of using Valaciclovir generichealth when pregnant and during breastfeeding.**

**Do not take Valaciclovir generichealth if the expiry date (EXP) printed on the pack has passed.**

**Do not take Valaciclovir generichealth if the packaging is torn or shows signs of tampering.**

*Before you start to take it*

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

**Tell your doctor if you are pregnant or plan to become pregnant.**

Your doctor will discuss the risks and benefits of taking Valaciclovir generichealth during pregnancy.

**Tell your doctor if you are breastfeeding or wish to breastfeed.**

Your doctor will discuss the risks and benefits of taking Valaciclovir generichealth when breastfeeding.

**Tell your doctor if you have, or have had, any medical conditions, especially the following:**

- anaemia;
- a kidney or liver condition.

**If you have not told your doctor about any of the above, tell them before you start taking Valaciclovir generichealth.**

*Taking other medicines*

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

Some medicines may be affected by Valaciclovir generichealth, or may affect how well it works. These include:

- mycophenolate mofetil;
- cyclosporin;
- tacrolimus.

These medicines are commonly taken by transplant patients and require close attention.

Your doctor can tell you what to do if you are taking any of these medicines.

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Valaciclovir generichealth.

### *Use in children*

There is not enough information to recommend the use of Valaciclovir generichealth in children.

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## How to take Valaciclovir generichealth

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

### *How much to take*

The dose varies from patient to patient.

The usual dose for adults and children over 12 years of age is 4 x 500 mg tablets (2 grams) four times a day for 90 days.

Patients with kidney disease may need a reduced dose.

### *How to take it*

Swallow the tablets with a glass of water.

### *When to take it*

For the prevention of CMV infection, Valaciclovir generichealth must be taken 4 times a day (morning, noon, afternoon and evening).

### *How long to take it*

**Keep taking Valaciclovir generichealth for as long as your doctor recommends.**

Valaciclovir generichealth is usually taken for 90 days.

### *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 the missed dose as soon as you remember, and then go back to taking your tablets 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 take too much (overdose)*

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

You may need urgent medical attention.

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## While you are taking Valaciclovir generichealth

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### *Things you must do*

Before starting any new medicine, tell your doctor or pharmacist that

you are taking Valaciclovir generichealth.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Valaciclovir generichealth.

If you become pregnant or are trying to become pregnant or intend to breastfeed while you are taking Valaciclovir generichealth, tell your doctor.

Visit your doctor regularly so they can check on your progress.

Drink plenty of fluids while you are taking Valaciclovir generichealth.

### *Things you must not do*

Do not use Valaciclovir generichealth to treat any other conditions unless your doctor tells you to.

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

Do not stop taking Valaciclovir generichealth tablets, or alter the dose, without first checking with your doctor.

**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.

### *Things to be careful of*

**Be careful driving or operating machinery until you know how Valaciclovir generichealth affects you.**

Valaciclovir generichealth does not normally affect alertness; however, make sure you know how Valaciclovir generichealth affects you before driving, operating machinery or anything else that could be dangerous.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Valaciclovir generichealth.**

Like all other medicines, Valaciclovir generichealth may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**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:**

- headache;
- gastrointestinal discomfort such as vomiting, nausea, diarrhoea, constipation, abdominal pain and indigestion;
- dry mouth;
- fever;
- difficulty sleeping;
- chills;
- back pain;
- nervousness;
- skin rash which may be itchy;
- weakness.

These should be reported to the doctor or pharmacist if they are severe or become troublesome.

**Tell your doctor if you notice any of the following side effects which are more common in patients with kidney disease or those taking high doses of Valaciclovir generichealth:**

- hallucinations;
- confusion;
- dizziness;
- drowsiness.

**Allergic reactions to Valaciclovir generichealth are rare. However, if you think you are having an allergic reaction, tell your doctor**

**immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:**

- wheezing;
- swelling of the lips or mouth;
- difficulty in breathing;
- hay fever;
- lumpy rash;
- fainting.

Rare side effects of Valaciclovir generichealth include unusual bruising or bleeding.

**Tell your doctor immediately if you notice any bruising or bleeding, as this may indicate that your blood is not clotting properly.**

**Some rare side effects of Valaciclovir generichealth are as follows:**

- sensitivity to UV light, such as development of a rash like sunburn even after short exposure to UV light. Talk to your doctor or pharmacist if you experience this;
- damage to kidney, which get better when Valaciclovir generichealth treatment is stopped;
- damage to liver, which get better when Valaciclovir generichealth treatment is stopped.

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.**

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## After taking Valaciclovir generichealth

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### *Storage*

**Keep Valaciclovir generichealth 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.

**Keep your tablets in their pack until it is time to take them.**

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

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

**Do not store Valaciclovir generichealth or any other medicine in the bathroom or near a sink.**

**Do not leave Valaciclovir generichealth in the car or on window sills.**

Heat and dampness can destroy some medicines.

### *Disposal*

**If your doctor tells you to stop taking Valaciclovir generichealth, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product description

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### *What it looks like*

Valaciclovir generichealth 250 mg is an oval, white, biconvex, film-coated tablets marked with VC1 on one side.

Valaciclovir generichealth 500 mg is an oval, white, biconvex film-coated tablet marked with VC2 on one side.

Valaciclovir generichealth 1000 mg is an oval, white, biconvex, film-coated tablets, marked with VC3 on one side.

Each pack contains 10, 30, 42 or 100 tablets.

Not all strengths and pack sizes may be marketed.

### *Ingredients*

#### **Active ingredient**

Each Valaciclovir generichealth tablet contains 250 mg, 500 mg or 1000 mg of valaciclovir (as hydrochloride monohydrate).

**Other ingredients**

- microcrystalline cellulose;
- povidone;
- magnesium stearate;
- Opadry White Y-5-7068 (PI 11771).

The tablets do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

***Australian Registration Numbers***

Valaciclovir generichealth 250 mg:  
AUST R 170175.

Valaciclovir generichealth 500 mg:  
AUST R 170178.

Valaciclovir generichealth 1000 mg:  
AUST R 170194

***Sponsor***

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This leaflet was prepared in July 2019.