

VACLOVIR®

for Cytomegalovirus

valaciclovir (as hydrochloride)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about VACLOVIR.

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 VACLOVIR 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.

What VACLOVIR is used for

VACLOVIR belongs to a group of medicines called antivirals.

VACLOVIR is used to prevent cytomegalovirus (CMV) infection and disease, following solid organ transplantation. CMV is another type of herpes virus. It can cause symptoms similar to glandular fever (high temperature, sore throat and swollen glands). VACLOVIR can help prevent CMV infection and herpes simplex infections.

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

VACLOVIR is not addictive.

Before you take VACLOVIR

When you must not take it

Do not take VACLOVIR if you have an allergy to:

- any medicine containing (valaciclovir, aciclovir)
- 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

Do not take this medicine if you are pregnant or are trying to become pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

Your doctor will discuss the risks and benefits of using VACLOVIR tablets when pregnant and during breastfeeding.

Do not give this medicine to children.

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

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 you take them after the expiry date has passed, they may not work as well.

If you are not sure whether you should be taking VACLOVIR, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- you have a kidney or liver condition.
- are anaemic (reduced red blood cells or iron stores)
Care should be taken to ensure adequate fluid intake in patients who are at risk of dehydration, such as the elderly.
- previous skin reactions with VACLOVIR which may include a rash, fever, facial swelling or blistering/peeling skin.
- you are pregnant or plan to become pregnant. Your doctor will discuss the risk and benefit of taking VACLOVIR when pregnant.

If you have not told your doctor about any of the above, please do so before you take VACLOVIR.

Taking other medicines

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

Some medicines may affect the way others work.

Tell your doctor if you are taking any of the following medicines:

- mycophenolate mofetil
- ciclosporin
- tacrolimus
- aminoglycosides
- organoplatinum compounds
- iodinated contrast media
- methotrexate
- pentamidine
- foscarnet

These medicines may be affected by VACLOVIR or VACLOVIR may be affected by these medicines. Mycophenolate mofetil, ciclosporin and tacrolimus are medicines commonly taken by transplant patients and require close attention. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take VACLOVIR

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

They may differ from the information contained in this leaflet.

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

How much to take

If you have been prescribed VACLOVIR tablets to prevent CMV infection and disease, the usual dose for adults and children over 12 years of age is four 500mg tablets four times a day for 90 days.

If you have a kidney disease your doctor may reduce your dose.

If you think you have been advised to take a different dose, talk to your doctor or pharmacist.

How to take it

Swallow the tablets with a glass of water.

You should drink plenty of fluids while taking VACLOVIR, especially if you are elderly.

When to take it

To prevent CMV infection and disease, the tablets should be taken four times a day (i.e. morning, noon, afternoon and evening).

It does not matter if you take this medicine before or after food.

How long to take it

For the prevention of CMV infection and disease, the usual course of treatment is 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 it as soon as you remember, then go back to taking it as you would normally.

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

If you miss more than one dose, or 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 Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much VACLOVIR, 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 VACLOVIR

Things you must do

Tell your doctor or pharmacist that you are taking VACLOVIR if you are about to be started on any new medicines.

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.

Tell your doctor if you become pregnant or are trying to become pregnant or intend to breastfeed while you are taking VACLOVIR.

Drink plenty of fluids while you are taking VACLOVIR.

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.

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.

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

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

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use VACLOVIR to treat any other conditions unless advised by your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

Side effects

Check with your doctor as soon as possible if you have any problems while taking this medicine, even if you do not think the problems relate to the medicine or are not listed in this leaflet.

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

This medicine helps most people with cytomegalovirus (CMV) infection and disease but it may have unwanted side effects in some 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 list of side effects.

You may not experience any of them.

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

The most commonly reported side effects are:

- headache
- gastrointestinal discomfort (vomiting, nausea, diarrhoea, constipation, abdominal pain, indigestion)

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

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

- dry mouth
- fever
- difficulty sleeping
- chills

- back pain
- nervousness
- skin rash which may be itchy
- weakness

You should contact your doctor as soon as possible if you experience any of the following side effects which are more common in patients with kidney disease or in those taking high doses of VACLOVIR:

- sensitivity to UV light, such as development of a rash like sunburn even after short exposure to UV or sunlight
- dizziness, confusion or imagining sight or sounds (hallucinations), difficulty in thinking
- drowsiness or decreased consciousness
- tiredness, dizziness, or being short of breath when exercising (signs of anaemia)
- high blood pressure

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

- damage to the kidney, which gets better when VACLOVIR treatment is stopped
- unusual bruising or bleeding
Tell your doctor immediately if you notice any bruising or bleeding, as it may indicate that the number of platelets (a type of blood cell responsible for blood clotting) in your blood are reduced.
- skin reactions which may include a rash, fever, facial swelling or blistering or peeling skin
- damage to the liver, which gets better when VACLOVIR treatment is stopped.
- agitation or tremor
- uncoordinated eye and muscle movements and speech or difficulty speaking
- psychotic episodes
- convulsions or seizures or coma

- brain injury

Some people are allergic to medicines. Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following:

- cough
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- hay fever
- rash, itching or hives on the skin
- fainting
- **If you think you are having an allergic reaction to VACLOVIR, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital.**
- **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 if you notice anything else that is making you feel unwell, even if it is not on this list.

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.

Some of these side effects, for example changes in kidney or liver function, can only be found when your doctor does tests from time to time to check your progress.

After taking VACLOVIR

Storage

Keep this medicine 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.

Keep VACLOVIR in a cool, dry place where it stays below 25°C. Do not store them, or any other medicine, in a bathroom or near a sink.

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

Heat and dampness can destroy some 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.

Disposal

If your doctor tells you to stop taking VACLOVIR, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Millers Point NSW 2000

www.viatrix.com.au

Phone: 1800 274 276

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Australian registration numbers:

VACLOVIR 500 mg tablets:

AUST R 153822 (blister pack)

AUST R 153823 (bottle)

VACLOVIR® is a Viatrix company trade mark

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Product description

What it looks like

VACLOVIR tablets are white coloured, oval shaped, biconvex film coated tablet with break line on one side and plain on the other side.

VACLOVIR tablets are available in:
Blister packs of 10, 30 and 42 tablets.
Bottles of 30 tablets.

Ingredients

VACLOVIR contains 500 mg of valaciclovir as the active ingredient.

The tablets also contain:

- microcrystalline cellulose
- magnesium stearate
- Opadry complete film coating system White OY-58900 (ARTG PI No: 3446)

Supplier

VACLOVIR is supplied by:

Alphapharm Pty Ltd trading as Viatrix

Level 1, 30 The Bond
30-34 Hickson Road