

VALACICLOVIR VIATRIS

Valaciclovir 500 mg Tablets



What is in this leaflet

Please read this leaflet carefully before you start taking Valaciclovir Viatris.

This leaflet answers some common questions about Valaciclovir Viatris 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 Valaciclovir Viatris 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 Valaciclovir Viatris is used for

Valaciclovir Viatris contains the active ingredient valaciclovir hydrochloride. It belongs to a group of medicines called antivirals.

Valaciclovir Viatris tablets are used for the treatment of shingles (herpes zoster). Valaciclovir Viatris tablets work by stopping multiplication of the virus which causes shingles. They can reduce the length and severity of an outbreak of shingles, as well as the pain associated with shingles. It is important the treatment is started within the first three days of a shingles attack.

Valaciclovir Viatris tablets are used for the treatment of infections of the skin and other mucous membranes (including the genitals) caused by the herpes simplex virus (HSV). Valaciclovir Viatris tablets work by stopping the multiplication of the herpes virus. They can reduce the length and severity of an outbreak of herpes, the duration of pain, and shorten the time to healing of crusts associated with herpes. They do not eliminate the herpes virus from the body.

Valaciclovir Viatris can help the blisters heal more quickly. If you start taking them as soon as you feel an outbreak starting, you may actually prevent the blisters developing. Valaciclovir Viatris tablets can also be taken long term to help prevent the herpes simplex virus infection coming back.

Valaciclovir Viatris (or any other antiviral) is not a cure for genital herpes. Because genital herpes is a sexually transmitted disease, you should minimise having intercourse when you have an outbreak of herpes or show any symptoms, and always use condoms. This will avoid the risk of spreading herpes to your partner. Patients should further reduce the risk of infecting partners by avoiding contact with lesions and damaged skin/mucosa, and avoid intercourse when lesions and/or symptoms are present.

Valaciclovir Viatris tablets are also used to prevent cytomegalovirus (CMV) infection and disease, following organ transplantation. CMV is another type of herpes virus.

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why this

medicine has been prescribed for you.

Valaciclovir Viatris is not addictive.

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

There is no information available on the use of this medicine in children.

Before you take Valaciclovir Viatris

When you must not take it

Do not take Valaciclovir Viatris if you have an allergy to:

- any medicine containing valaciclovir or 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 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.

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:

- kidney or liver disease
- anaemia or other blood disorders
- HIV
- organ transplant

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding. Your doctor can discuss with you the risks and benefits involved.

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

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.

You should also tell any health professional who is prescribing a new medication for you that you are taking Valaciclovir Viatris.

Some medicines and Valaciclovir Viatris may interfere with each other. These include:

- mycophenolate mofetil and tacrolimus, immunosuppressant medicines used to prevent organ rejection in transplant patients
- ciclosporin
- aminoglycosides
- organoplatinum compounds
- iodinated contrast media
- methotrexate
- pentamidine
- foscarnet

These medicines may be affected by Valaciclovir Viatris 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 have more information on medicines to

be careful with or avoid while taking this medicine.

How to take Valaciclovir 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 box, ask your doctor or pharmacist for help.

How much to take

Treatment of Shingles

The usual dose to take is two 500 mg tablets three times a day for seven days.

Treatment of HSV Infection

The usual dose to take is one 500 mg tablet twice a day. Treatment is usually for five days, but can be extended to ten days in some cases.

Prevention of HSV Infection

The usual dose to take is one 500 mg tablet once a day.

If your immune system is suppressed, the recommended dose is one 500 mg tablet twice a day.

If you have had a herpes infection before, you should start to take Valaciclovir Viatris tablets as early as possible if you think you are about to have another attack. Dosing should ideally start just before, or straight after the first signs of HSV infection appear.

Prevention of CMV Infection and Disease

The usual dose for adults and children over 12 years of age following organ transplant is four 500 mg tablets four times a day. Treatment is usually for 90 days, but can be longer in some cases.

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

How to take it

Swallow the tablets whole with a full glass of water.

It is important to drink plenty of fluids while taking Valaciclovir Viatris tablets, especially if you are elderly or have kidney disease.

When to take it

Take your Valaciclovir Viatris tablets as prescribed by your doctor.

Take your medicine at about the same time each day.

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

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

For shingles, the usual course of treatment is seven days.

For the treatment of herpes infections, the usual course of treatment is five days. However, in some instances your doctor may want you to take your tablets for ten days.

For the prevention of herpes infections, you should continue to take your medicine every day as prescribed by your doctor.

For the prevention of CMV infection and disease, the usual course of treatment is 90 days.

Do not stop taking Valaciclovir Viatris tablets before the course of treatment is finished, even if you feel better.

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 your medicine as you would normally.

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

While you are taking Valaciclovir Viatris

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Valaciclovir Viatris.

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 or intend to breastfeed 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.

Drink plenty of fluids while you are taking Valaciclovir Viatris tablets.

Keep all of 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 take Valaciclovir Viatris 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 or lower the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

Be careful driving or operating machinery until you know how Valaciclovir Viatris affects you. This medicine may cause dizziness, headache, confusion, hallucination or decreased consciousness in some people. If you have this symptom, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Valaciclovir Viatris. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include confusion, hallucinations, agitation, decreased consciousness, coma, nausea, vomiting and kidney failure.

Side effects

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

This medicine helps most people, 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 treatment if you get some of the side effects.

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:

- headache
- gastrointestinal discomfort (vomiting, nausea, diarrhoea, constipation, abdominal pain, indigestion)
- dry mouth
- fever
- difficulty sleeping
- chills
- back pain
- nervousness
- skin rash, which may be itchy
- weakness
- feeling aggressive

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

- sensitivity to UV light, which may include development of a rash-like sunburn even after short period of exposure to UV or sunlight
- dizziness, confusion, imagining sights 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
- painful urination
- lower back or side pain

The above side effects are more common in patients with kidney disease or in those taking high doses, and may require medical attention.

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 valaciclovir 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 valaciclovir 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
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

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

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

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

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

After taking Valaciclovir Viatris

Storage

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

If you take the tablets out of the 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 Viatris 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

Valaciclovir Viatris 500 mg tablets are white to off white, capsule shaped, biconvex film-coated tablets with "VC 500" on one side and "G" on the other side.

Ingredients

Active ingredient:

Valaciclovir Viatris contains 500 mg of valaciclovir (as valaciclovir hydrochloride) as the active ingredient.

Inactive ingredients:

Valaciclovir Viatris also contains:

- microcrystalline cellulose
- povidone
- crospovidone
- magnesium stearate
- hypromellose
- macrogol
- titanium dioxide
- polysorbate

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Valaciclovir Viatris is supplied in New Zealand by:

Viatri Ltd,
PO Box 11-183,
Ellerslie,
AUCKLAND
www.viatri.co.nz
Telephone: 0800 168 169

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