

Valaciclovir Sandoz®

for herpes zoster, herpes labialis, herpes simplex and cytomegalovirus

Valaciclovir hydrochloride film-coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Valaciclovir Sandoz.

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 this medicine 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 Sandoz is used for

How Valaciclovir Sandoz works

This medicine belongs to a group of medicines called antivirals. Valaciclovir Sandoz tablets are used for the treatment of genital herpes, shingles (herpes zoster), ophthalmic zoster (shingles affecting the eye region) and cold sores (herpes labialis). It also used to prevent cytomegalovirus (CMV) infection and disease following solid organ transplantation. CMV is another type of herpes virus that can cause symptoms similar to glandular fever

(high temperature, sore throat and swollen glands).

Valaciclovir Sandoz works by stopping the multiplication of the viruses which causes herpes, shingles and cold sores. It can reduce the length and severity of an outbreak of shingles and cold sores and the duration of pain, and shorten the healing time of crusts, associated with shingles and cold sores. Valaciclovir Sandoz does not eliminate the herpes virus (Herpes Simplex Virus or HSV) from the body.

It is important the treatment for shingles is started within the first three days of the shingles attack.

For the treatment of cold sores the tablets should be taken at the earliest symptom of a cold sore (e.g. tingling, itching, or burning).

For the treatment of herpes simplex, start taking the tablets as soon as you feel an outbreak starting, as you may prevent the blisters from developing, or help the blisters to heal more quickly.

Valaciclovir Sandoz tablets can also be taken long term to help prevent or reduce recurrent outbreaks of HSV and reduce the risk of transmitting the virus that causes genital herpes but does not cure or completely eliminate the risk of transmission.

This medicine is more effective in patients 50 years of age and older.

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

Valaciclovir Sandoz tablets are available with a doctor's prescription.

This medicine is not addictive.

Before you take Valaciclovir Sandoz

When you must not take it

Do not take this medicine:

- **if you have ever had an allergic reaction to valaciclovir hydrochloride, the active ingredient, aciclovir or any of the ingredients listed at the end of this leaflet under Product description.** Refer to section "Side Effects" for some common symptoms of an allergic reaction.
- **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 this medicine when pregnant and during breast feeding.
- **after the expiry date (EXP) printed on the pack.** If you take it after expiry date has passed, it may not work as well.
- **if the packaging is torn or shows signs of tampering.**

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if

- you have allergies to any other medicines, foods, preservatives or dyes
- you have a kidney or liver condition
- you 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 valaciclovir which may include a rash, fever, facial swelling or blistering/ peeling skin

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

Taking other medicines

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

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

- Mycophenolate mofetil
- Cyclosporin
- Tacrolimus
- Aminoglycosides
- Organoplatinum compounds
- Iodinated contrast media
- Methotrexate
- Pentamidine
- Foscarnet

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking Valaciclovir Sandoz with other medicines.

Some of the medicines above are 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.

Use in children

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

How to take Valaciclovir Sandoz

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

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you:

- how many tablets to take at each dose
- how many doses to take each day
- when to take your doses easy day.

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

How much to take for the prevention of CMV infection and disease

The usual dose for adults and children over 12 years of age is four 500 mg tablets four times a day for 90 days.

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

How much to take for the treatment of shingles

If you have been prescribed Valaciclovir Sandoz 500 mg Tablets, the normal dose to take is two tablets with water three times a day.

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

How much to take for the treatment of cold sores

If you have been prescribed Valaciclovir Sandoz 500 mg tablets, the normal dose to take for the one

day regimen is four tablets with water twice a day, with the second dose taken about 12 hours after the first dose.

How much to take for the treatment of acute (short term) genital herpes:

If you have had a herpes infection before, you should start to take Valaciclovir Sandoz tablets as early as possible if you think you are about to have another recurrence (attack). Dosing should ideally start just before, or straight after the first signs of HSV infection appear. For the treatment of HSV infection, the usual dose to take is one tablet with water twice daily

How much to take for suppressive (long term) treatment of genital herpes:

To prevent the herpes infection appearing again, the usual dose to take is 500 mg once daily. Your doctor may recommend that you take this as a divided dose (i.e. 250 mg twice daily).

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 whole with a full glass of water.

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

Do not chew the tablets.

When to take Valaciclovir Sandoz

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

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.

For the prevention of CMV infection and disease, the tablets should be taken four times a day

(i.e. morning, noon, afternoon or evening).

For the treatment of shingles the usual times to take the tablets are in the morning, afternoon and evening.

For the treatment of cold sores the tablets should be taken at the earliest symptom of a cold sore (e.g tingling, itching, or burning). Treatment for cold sores should not exceed 1 day (2 doses) and the doses should be taken 12 hours apart.

For the treatment of herpes simplex infections (genital herpes), the usual times to take the tablets are in the morning and evening.

How long to take Valaciclovir Sandoz

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

For shingles the usual course of treatment is seven days.

Do not stop taking your medicine before the course of treatment is finished just because you feel better. The shingles may not be completely over.

For cold sores the course of treatment should not exceed 1 day (2 doses) and the doses should be taken 12 hours apart.

For the treatment of herpes simplex (genital herpes), the usual course of treatment is 5 days. However, in some instances your doctor may want you to take your tablets for 10 days.

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

Do not stop taking Valaciclovir Sandoz tablets just because you feel better. The herpes outbreak may not be completely over.

If you forget to take it

For prevention of CMV infection and disease, the treatment of

shingles or the treatment of herpes simplex (genital herpes), 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.

For the treatment of cold sores, take the second dose as soon as possible once the 12 hours have passed.

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

If you miss more than one dose or 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 the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Valaciclovir Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Valaciclovir Sandoz

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 Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant or are trying to become pregnant or intend to breastfeed while taking this medicine, tell your doctor immediately.

Drink plenty of water while you are taking Valaciclovir Sandoz.

If you are going to have surgery, tell your surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Tell your doctor if your symptoms are not improving or are worsening while you are taking Valaciclovir Sandoz.

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.

It is recommended that patients using Valaciclovir Sandoz continuously to prevent or reduce recurrent outbreaks, or to reduce the risk of transmitting the virus that causes genital herpes, also avoid contact when symptoms are present and always use condoms.

Valaciclovir Sandoz does not cure genital herpes or completely eliminate the risk of transmission. Because genital herpes is a sexually transmitted disease, you should minimise having intercourse when you have an outbreak of herpes or show any symptoms. This will avoid the risk of spreading the herpes to your partner.

Things you must not do

Do not take Valaciclovir Sandoz 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 Valaciclovir Sandoz, or change the dose, without first checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Valaciclovir Sandoz tablets affect you.

Side effects

Tell your doctor or pharmacist as soon as possible if you have any problems while taking Valaciclovir Sandoz tablets, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

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.

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

If you think you are having an allergic reaction to Valaciclovir Sandoz tablets, stop taking the tablets and tell your doctor immediately or to the casualty department at your nearest hospital.

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 as soon as possible if you notice any of the following. Some of these side effects are more common in patients with kidney disease or in those taking high doses of Valaciclovir Sandoz:

- sensitivity to UV light, such as development of a rash like sunburn even after short 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

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

- damage to the kidneys, which gets better when Valaciclovir Sandoz 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 our 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 Sandoz treatment is stopped
- agitation or tremor
- psychotic episode
- convulsions or seizures or coma
- brain injury
- uncoordinated eye and muscle movements and speech or difficulty speaking
- 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.

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

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

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

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

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 Valaciclovir Sandoz

Storage

Keep your tablets in the original container.

If you take it out of its original container it may not keep well.

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

Do not store Valaciclovir Sandoz 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 Sandoz 500mg film-coated tablets - white to off-white capsule shaped film coated tablets with '500' debossed on one side and plain on other side.

Available in blister packs of 10, 30 and 42 film-coated tablets.

Ingredients

Active ingredients:

- Valaciclovir hydrochloride

Inactive ingredients:

- microcrystalline cellulose
- crospovidone
- povidone
- magnesium stearate
- Opadry White 13B58802.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
100 Pacific Highway
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Australia
Tel 1800 726 369

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Australian Register Number

Valaciclovir Sandoz 500mg film-coated tablets: AUST R 154464.