

Valaciclovir Sandoz®

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

This medicine is used to treat:

- genital herpes infections (Herpes Simplex Virus, or HSV)
- shingles (herpes zoster) and ophthalmic zoster (shingles affecting the eye region).

This medicine is also 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).

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

It works by stopping the multiplication of the viruses which cause these infections.

For genital herpes infections:

Although Valaciclovir Sandoz does not cure the infection, it can reduce the length and severity of an outbreak of herpes, the duration of pain and shorten the time to healing. It also helps blisters to heal more quickly. If you start taking them as soon as you feel an outbreak starting, you may prevent the blisters from developing.

This medicine (or any other antiviral) does not cure genital herpes or completely eliminates the risk of transmission. Genital herpes is a sexually transmitted disease. Therefore, in addition to therapy with this medicine, it is recommended that you should minimize having intercourse when you have an outbreak of herpes or show any symptoms. Condoms should always be used. This will reduce the risk of spreading herpes to your partner.

For shingles affecting the body and eye region:

This medicine can reduce the length and severity of an outbreak of shingles and the duration of pain associated with shingles. It is important the treatment is started within the first three days of the shingles attack.

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

This medicine is not addictive.

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

There is not enough information to recommend the use of this medicine for children under the age of 12 years.

Before you take Valaciclovir Sandoz

When you must not take it

Do not take this medicine if you have an allergy to:

- valaciclovir hydrochloride, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product description.
- any other similar medicines (such as aciclovir).

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 condition
- liver condition.

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 Sandoz.

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.

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

- aminoglycosides, organoplatinum compounds, iodinated contrast media, methotrexate, pentamidine, foscarnet, ciclosporin, and tacrolimus.
- cimetidine, a medicine used to treat heartburn or peptic ulcers
- probenecid, a medicine used to treat gout
- immunosuppressant medicines such as mycophenolate mofetil, ciclosporin and tacrolimus. These medicines are commonly taken by transplant patients and require close attention.

These medicines may be affected by Valaciclovir Sandoz 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 Sandoz

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, ask your doctor or pharmacist for help.

How much to take

For acute (short term) treatment of genital herpes:

If you have had a herpes infection before, you should start to take Valaciclovir Sandoz as early as possible if you think you are about to have another recurrence (attack). This medicine should ideally be taken just before or straight after the first signs of HSV infection appear.

The usual dose to take is one 500mg tablet with water twice daily.

To treat shingles affecting the body and eye region:

The usual dose to take is 1000mg (two 500mg tablets) with water three times a day.

To prevent CMV infection and disease:

The usual dose for adults and children over 12 years of age is 2000mg (four 500mg tablets) with water four times a day.

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

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Valaciclovir Sandoz may not work as well.

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 them.

When to take Valaciclovir Sandoz

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 genital herpes infections:

The usual times to take the tablets are in the morning and evening.

For shingles affecting the body and eye region:

The usual times to take the tablets are in the morning, afternoon and evening.

To prevent CMV infection and disease:

The tablets should be taken four times a day (i.e. morning, noon, afternoon and evening).

How long to take Valaciclovir Sandoz

For genital herpes infections:

For the treatment of herpes infections, the usual course of treatment is five days.

However in some instances the doctor may want you to take your tablets for ten days.

For shingles affecting the body and eye region:

The usual course of treatment is seven days.

To prevent CMV infection and disease:

The usual course of treatment is 90 days.

Do not stop taking your medicine before the course of treatment is finished because you feel better, unless otherwise advised by your doctor.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

This may increase the chance of you getting an unwanted side effect.

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.

Symptoms of an overdose may include:

- agitation
- confusion or imagining sights or sounds (hallucinations)
- drowsiness
- nausea and vomiting.

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.

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.

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 heavy machinery until you know how Valaciclovir Sandoz affects you.

This medicine may cause dizziness, confusion and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Valaciclovir should be discontinued if central nervous system adverse reactions occur.

Side effects

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

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.

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

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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 and chills
- difficulty sleeping
- back pain
- nervousness
- skin rash which may be itchy
- weakness
- sensitivity to UV light, such as development of a rash like sunburn even after short exposure to UV light.

For patients taking Valaciclovir Sandoz for the prevention of CMV infection and disease, you should report the above side effects to the doctor or pharmacist if they are severe or become troublesome.

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

- dizziness
- confusion or imagining sights or sounds (hallucinations)
- drowsiness.

These side effects are more common in patients with kidney disease or in those taking high doses of Valaciclovir Sandoz (for the prevention of CMV infection and disease).

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

- damage to the kidneys, which gets better when Valaciclovir Sandoz is stopped. Symptoms of severe damage to the kidneys includes lower back pain

(kidney pain), little or no urine, drowsiness, nausea, vomiting or breathlessness.

The above is a serious side effect that may require medical attention. Serious side effects are rare.

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

- unusual bruising or bleeding, which may indicate that your blood is not clotting properly
- allergic reaction. 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.

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

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

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

Some side effects (for example hypertension (high blood pressure), damage to the liver or kidneys) 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 Sandoz 500mg - 556.275mg valaciclovir hydrochloride (equivalent to 500 mg of valaciclovir)

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

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