

Valaciclovir Sandoz®

for herpes zoster and herpes labialis

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 shingles (herpes zoster), ophthalmic zoster (shingles affecting the eye region) and cold sores (herpes labialis).

Valaciclovir Sandoz works by stopping the multiplication of the viruses which cause shingles and cold sores.

This medicine can reduce the length and severity of an outbreak of shingles and cold sores and the

duration of pain associated with shingles and cold sores.

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).

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

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

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.

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.

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.

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

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 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

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 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

How long to take Valaciclovir Sandoz

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.

If you forget to take it

For the treatment of shingles, 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 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.

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

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.

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.

The most commonly reported side effects are:

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

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:

- dry mouth
- fever
- difficulty sleeping

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

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: wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting.

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.

Some rare side effects of Valaciclovir Sandoz include:

- sensitivity to UV light, such as development of a rash like sunburn even after short exposure to UV light
- 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.
- damage to the liver, which gets better when Valaciclovir Sandoz treatment is stopped
- coma
- agitation
- tremor
- psychotic episode
- convulsions
- brain injury
- uncoordinated muscle movements and speech

You should contact your doctor 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 Valaciclovir Sandoz:

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

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

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.

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

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