VALACICLOVIR GENERICHEALTH

TREATMENT OF ZOSTER AND HERPES LABIALIS

 $(valacic lovir\ hydrochloride\ monohydrate)\ film\text{-}coated\ tablet$

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Valaciclovir generichealth.

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 Valaciclovir generichealth 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 Valaciclovir generichealth is used for

Valaciclovir generichealth is used to treat shingles (herpes zoster), ophthalmic zoster (shingles affecting the eye region) and cold sores (herpes labialis).

Valaciclovir generichealth belongs to a group of medicines called antivirals.

It works by stopping the multiplication of the virus which causes the shingles and cold sores. Valaciclovir generichealth reduces the length and severity of an outbreak and the duration of pain associated with the shingles and cold sores.

It is important to start treatment within three days of the shingles attack.

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

Valaciclovir generichealth tablets are more effective in patients 50 years and over.

Your doctor may have prescribed Valaciclovir generichealth for another reason. Ask your doctor if you have any questions about why Valaciclovir generichealth has been prescribed for you.

Valaciclovir generichealth is not recommended for use in children, as there have been no studies of its effects in children.

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

There is no evidence that Valaciclovir generichealth is addictive.

Before you take Valaciclovir generichealth

When you must not take it

Do not take Valaciclovir generichealth if you are allergic to:

- medicines containing valaciclovir, aciclovir;
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, hayfever, wheezing or shortness of breath or fainting.

Do not take Valaciclovir generichealth 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 Valaciclovir generichealth when pregnant and during breastfeeding.

Do not take Valaciclovir generichealth if the expiry date (EXP) printed on the pack has passed.

Do not take Valaciclovir generichealth if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking Valaciclovir generichealth during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking Valaciclovir generichealth when breastfeeding.

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

anaemia;

· kidney or liver condition.

If you have not told your doctor about any of the above, tell them before you start taking Valaciclovir generichealth.

Taking other medicines

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

Some medicines may be affected by Valaciclovir generichealth, or may affect how well it works. These include:

- · mycophenolate mofetil;
- · cyclosporin;
- tacrolimus.

These medicines are commonly taken by transplant patients and require close attention.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Valaciclovir generichealth.

Use in children

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

How to take Valaciclovir generichealth

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

How much to take

For the treatment of shingles

If you have been prescribed Valaciclovir generichealth 500 mg

tablets, the normal dose to take is 2 tablets with water three times a day.

For the treatment of cold sores

If you have been prescribed Valaciclovir generichealth 500 mg tablets, the normal dose to take for the one day regimen is 4 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 with a glass of water.

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 (eg. 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 it

For the treatment of shingles

For shingles the usual course of treatment is 7 days

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

For the treatment of cold sores

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

If you forget to take it

For 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.

For treatment of cold sores

Take the second dose as soon as possible once 12 hours have passed.

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

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons
Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Valaciclovir generichealth. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Valaciclovir generichealth

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Valaciclovir generichealth.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Valaciclovir generichealth.

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.

Drink plenty of fluids while you are taking Valaciclovir generichealth.

Things you must not do

Do not stop taking Valaciclovir generichealth tablets, or alter the dose, without first checking with your doctor.

Do not use Valaciclovir generichealth to treat any other conditions unless your doctor tells you to.

Do not give Valaciclovir generichealth to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Valaciclovir generichealth affects you.

Valaciclovir generichealth does not normally affect alertness; however, make sure you know how Valaciclovir generichealth affects you before driving, operating machinery or anything else that could be dangerous.

Side effects

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

Like all other medicines, Valaciclovir generichealth may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- · headache;
- gastrointestinal discomfort (vomiting, nausea, diarrhoea, constipation, abdominal pain and indigestion);
- 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 lips/mouth, difficulty in breathing, hay fever, lumpy rash (hives) or fainting.

If you think you are having a allergic reactions to Valaciclovir generichealth tablets stop taking the tablets and tell your doctor immediately or go to Accident and Emergency at the nearest hospital.

Some rare side effects of Valaciclovir generichealth are as follows:

- sensitivity to UV light, such as development of a rash like sunburn even after short exposure to UV light swelling of the lips or mouth;
- · unusual bruising or bleeding.
- damage to kidney, which get better when Valaciclovir generichealth treatment is stopped;
- damage to liver, which get better when Valaciclovir generichealth treatment is stopped.

Tell your doctor immediately if you notice any bruising or bleeding, as this may indicate that your blood is not clotting properly.

Tell your doctor if you notice any of the following side effects which are more common in patients with kidney disease or those taking high doses of Valaciclovir generichealth:

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

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

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

After taking Valaciclovir generichealth

Storage

Keep Valaciclovir generichealth where children cannot reach it.

A locked cupboard at least one-anda-half metres above the ground is a good place to store medicines.

Keep your tablets in their 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 generichealth or any other medicine in the bathroom or near

Do not leave Valaciclovir generichealth in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

Valaciclovir generichealth 250 mg is an oval, white, biconvex, film-coated tablets marked with VC1 on one side.

Valaciclovir generichealth 500 mg is an oval, white, biconvex film-coated tablet marked with VC2 on one side.

Valaciclovir generichealth 1000 mg is an oval, white, biconvex, film-coated tablets, marked with VC3 on one side.

Each pack contains 10, 30, 42 or 100 tablets.

Not all strengths and pack sizes may be marketed.

Ingredients

Active ingredient

Each Valaciclovir generichealth tablet contains 500 mg of valaciclovir (as hydrochloride monohydrate).

Other ingredients

- · microcrystalline cellulose;
- povidone;
- magnesium stearate;
- Opadry White Y-5-7068 (PI 11771).

The tablets do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Australian Registration Numbers

Valaciclovir generichealth 250 mg: AUST R 170175.

Valaciclovir generichealth 500 mg: AUST R 170178.

Valaciclovir generichealth 1000 mg: AUST R 170194

Sponsor

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