

VACLOVIR

for Herpes Zoster and Herpes Labialis
valaciclovir (as hydrochloride)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VACLOVIR. 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 VACLOVIR 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 VACLOVIR is used for

VACLOVIR belongs to a group of medicines called antivirals.

VACLOVIR is used for the treatment of shingles (herpes zoster) and ophthalmic zoster (shingles affecting the eye region) and cold sores (herpes labialis).

VACLOVIR works by stopping the multiplication of the virus which causes shingles and cold sores. It can reduce the length and severity of an outbreak of shingles or 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 3 days of the shingles attack.

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

VACLOVIR 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.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

Before you take VACLOVIR

When you must not take it

Do not take VACLOVIR 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 if you are pregnant or are trying to become pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine

Your doctor will discuss the risks and benefits of taking VACLOVIR when pregnant or whilst breastfeeding.

Do not give this medicine to children.

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

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 be 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:

- you are anaemic (reduced red blood cells or iron levels)
Care should be taken to ensure adequate fluid intake occurs in patients who are at risk of dehydration, such as the elderly.
- previous skin reactions with Vaclovir which may include a rash, fever, facial swelling or blistering/peeling skin
- you have a kidney or liver condition
- you are pregnant or plan to become pregnant. Your doctor will discuss the risk and benefit of taking Vaclovir when pregnant.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a

prescription from a pharmacy, supermarket or health food shop.

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

- medicines used to suppress the immune system following organ transplant such as mycophenolate mofetil, ciclosporin, tacrolimus
- medicines used to treat bacterial infections such as aminoglycosides
- medicines used in the treatment of some cancers such as organoplatinum compounds,
- iodinated contrast media
- methotrexate
- medicines used to treat fungal infections such as pentamidine
- other medicines used to treat the virus which causes shingles and cold sores such as foscarnet

These medicines may be affected by VACLOVIR 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 VACLOVIR

Follow all directions given to you by your doctor and 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

Shingles

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

If you have been prescribed VACLOVIR 1000 mg tablets, the normal dose to take is one table with water three times a day.

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

Cold Sores

If you have been prescribed VACLOVIR 500 mg tablets, the normal dose to take is four tablets with water twice a day, for one day only. The second dose should be taken about 12 hours (and no fewer than 6 hours) after the first dose.

If you have been prescribed VACLOVIR 1000 mg tablets, the normal dose to take is two tablets with water twice a day, for

one day only. The second dose should be taken about 12 hours (and no fewer than 6 hours) after the first dose.

How to take it

Swallow the tablets whole with a glass of water.

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

When to take it

Shingles

Take the tablets in the morning, afternoon and evening.

Cold Sores

Take the tablets at the earliest sign of symptoms of a cold sore (e.g. tingling, itching or burning).

Take the second dose at least 12 hours after the first dose.

How long to take it

Shingles

The usual course of treatment is seven days. Do not stop taking Vaclovir before the course of treatment is finished just because you feel better. The shingles may not be completely over.

Cold Sores

The course of treatment should not exceed 1 day (2 doses) and the doses should be taken at least 12 hours apart.

If you forget to take it

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, and then go back to taking your medicine as you would normally.

If you have trouble remembering to take your medicine ask your pharmacist for some hints.

Cold Sores

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

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

If you miss more than one dose, or 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) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much

VACLOVIR. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking VACLOVIR

Things you must do

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

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

Tell your doctor if you become pregnant or are trying to become pregnant or intend to breastfeed while you are taking VACLOVIR.

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 VACLOVIR affects you.

Things you must not do

Do not take VACLOVIR 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 change the dose without checking with your doctor.

Side effects

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

This medicine helps most people with herpes zoster or herpes labialis virus 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 attention if you get some of the side effects.

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

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

The most commonly reported side effects are:

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

You should tell your doctor or pharmacist if they become severe or troublesome.

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 rare side effects of VACLOVIR include:

- damage to the kidney, which gets better when VACLOVIR 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 VACLOVIR treatment is stopped
- coma
- agitation
- tremor
- uncoordinated muscle movements and speech
- psychotic episodes
- convulsions
- 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

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 VACLOVIR:

- sensitivity to UV light, such as development of a rash like sunburn even after short exposure to UV or sunlight
- dizziness
- confusion or imagining sights or sounds (hallucinations)

- drowsiness
- decreased consciousness

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

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

After taking VACLOVIR

Storage

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

If you take the tablets out of the pack or bottle they may not keep well.

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

Do not store VACLOVIR, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in a 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

VACLOVIR tablets are white coloured, oval shaped, biconvex film coated tablet with break line on one side and plain on the other side.

VACLOVIR tablets are available in:

Blister packs of 8, 10, 30 and 42 tablets.

Bottles of 30 and 42 tablets.

Ingredients

VACLOVIR contains 500 mg of valaciclovir as the active ingredient.

The tablets also contain:

- microcrystalline cellulose
- magnesium stearate
- Opadry complete film coating system white OY-58900 (proprietary ingredient number: 3446)

The tablets are gluten free.

Supplier

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Australian registration numbers:

VACLOVIR 500 mg tablets:

AUST R 153822 (blister pack)

AUST R 153823 (bottle)

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