

VALTREX(R) Tablets

for herpes zoster and herpes labialis

valaciclovir

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Valtrex tablets. 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 risks and benefits. Your doctor has weighed the risks of you taking Valtrex tablets against the benefits this medicine is expected to 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 Valtrex tablets are used for

How Valtrex tablets Work

Valtrex tablets belong to a group of medicines called antivirals. Valtrex tablets are used for the treatment of shingles (herpes zoster), ophthalmic zoster (shingles affecting the eye region) and cold sores (herpes labialis).

Valtrex tablets work by stopping the multiplication of the virus which causes shingles and cold sores. They 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).

Valtrex tablets are more effective in patients 50 years of age and older.

Ask your doctor if you have any questions about why Valtrex tablets have been prescribed for you.

Valtrex tablets are not addictive.

Before you take Valtrex tablets

When you must not take them

* **Do not take Valtrex tablets if you have ever had an allergic reaction to valaciclovir, aciclovir or any of the ingredients listed at the end of this leaflet.**

Refer to "Side Effects" section for some common symptoms of an allergic reaction.

* **Do not take Valtrex tablets 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 Valtrex

tablets when pregnant and during breastfeeding.

* **Do not take Valtrex tablets after the expiry date (EXP) printed on the pack.**

If you take it after the expiry date has passed, it may not work as well.

* **Do not take Valtrex tablets if the packaging is torn or shows signs of tampering.**

If you are not sure whether you should be taking Valtrex, talk to your doctor.

Before you start to take them

You must tell your doctor if:

- * you are allergic to foods, dyes, preservatives or any other medicines.
- * you have a kidney or liver condition.

If you have not told your doctor about any of the above, please do so before you take Valtrex.

Taking other medicines

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

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

Use in children

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

How to take Valtrex tablets

Take Valtrex tablets exactly as your doctor has prescribed. 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 each day.

The label on the pack will give the same information. If there is something you do not understand, ask your doctor or pharmacist.

How much to take for the treatment of shingles

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

If you have been prescribed Valtrex 1000 mg tablets, the normal dose to take is one tablet 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 Valtrex 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.

If you have been prescribed Valtrex 1000 mg tablets, the normal dose to take for one day regimen is two tablets with water twice a day, with the second dose taken about 12 hours after the first dose.

How to take them

Swallow the tablets with a glass of water.

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

When to take them

The shingles and cold sore packs are designed to help you to remember to take the tablets at the correct times.

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 them

For shingles the usual course of treatment is seven days

Do not stop taking Valtrex tablets 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 them

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 the 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 take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much Valtrex tablets, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

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

While you are taking Valtrex tablets

Things you must do

Tell your doctor or pharmacist that you are taking Valtrex tablets if you are about to be started on any new medicines.

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

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 Valtrex tablets affect you.

Things you must not do

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

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Valtrex tablets to treat any other complaints unless your doctor says to.

Side Effects

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

Like all medicines, Valtrex tablets can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

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 Valtrex tablets, stop taking the tablets and tell your doctor immediately or go 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 Valtrex tablets include:

- * sensitivity to UV light, such as development of a rash like sunburn even after short exposure to UV light
- * damage to the kidney, which gets better when Valtrex 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.
- * Damage to the liver, which gets better when Valtrex treatment is stopped.

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 Valtrex:

- * Dizziness
- * Confusion or imagining sights or sounds (hallucinations)
- * Drowsiness.

Tell your doctor 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 Valtrex tablets

Storage

Keep this medicine where young children cannot reach it.

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

Keep Valtrex tablets in a cool, dry place where it stays below 30 degrees C. Do not store them, or any other medicine, in a bathroom or near a sink.

Do not leave them in the car or on window sills.

Heat and dampness can destroy some medicines

Keep your tablets in their pack until it is time to take them.

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

Disposal

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

Product description

What Valtrex tablets look like.

Valtrex 500 mg tablets are elongated white tablets marked with "GX CF1" on one side. They are available in a pack size of 8, 30, 42 and 100 tablets.

Valtrex 1000 mg tablets are elongated white tablets marked with "GX CF2" on one side. They are available in a pack size of 4 tablets and bottles of 4 tablets.

Ingredients

Valtrex tablets contain the active ingredient valaciclovir. The tablets also contain microcrystalline cellulose, crospovidone, povidone, colloidal anhydrous silica, carnauba wax, magnesium stearate, white colour concentrate, and blue printing ink.

Supplier

Your Valtrex tablets are made by:
GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia
Victoria, 3155
Australia.

Further Information

Pharmaceutical companies are not in a position to give people individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you individual advice. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

This leaflet was prepared on 12 August 2008.

The information provided applies only to: Valtrex(R) tablets.

Valtrex(R) is a registered trade mark of the GlaxoSmithKline Group of Companies.

Valtrex 500 mg tablets: AUST R 73917 (blister pack) AUST R 73918 (bottle)

Valtrex 1000 mg tablets: AUST R 73920 (blister pack) AUST R 73919 (bottle)

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