VALTREX® 500mg Tablets for cytomegalovirus

Valaciclovir

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start Valtrex tablets.

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

Valtrex tablets belong to a group of medicines called antivirals.

Valtrex tablets are 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). Valtrex tablets can help prevent CMV infection and herpes simplex infections.

Ask your doctor if you have any questions about why Valtrex tablets

have been prescribed for you. Your doctor may have prescribed it for another reason.

Valtrex tablets are not addictive.

Valtrex tablets are available only with a doctor's prescription.

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.

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, hay fever, lumpy rash ("hives") or fainting.

 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're not sure whether you should be taking Valtrex tablets, 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 are anaemic (reduced red blood cells or iron stores).
- you have a kidney or liver condition.
- you are pregnant or plan to become pregnant. Your doctor will discuss the risk and benefits of taking Valtrex when pregnant.

Care should be taken to ensure adequate fluid intake in patients who are risk of dehydration, such as the elderly.

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.

Mycophenolate mofetil, cylclosporin and tacrolimus are medicines commonly taken by transplant patients and require close attention. These medicines may be affected by Valtrex or Valtrex may be affected by these medicines.

Other medicines which may affect Valtrex include:

- · Aminoglycosides
- Organoplatinum compounds
- Iodinated contrast media
- Methotrexate
- Pentamidine
- Foscarnet

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 tablets 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

If you have been prescribed Valtrex tablets to prevent CMV infection and disease, the usual dose for adults and children over 12 years of age is four 500mg tablets four times a day for 90 days.

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

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

How to take them

Swallow the tablets whole with a glass of water.

You should drink plenty of fluids while taking Valtrex tablets.

When to take them

To prevent CMV infection and disease, the tablets should be taken four times a day (ie. morning, noon, afternoon and evening).

It does not matter if you take this medicine before or after food.

How long to take them

For the prevention of CMV infection and disease, the usual course of treatment is 90 days.

If you forget to take them

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 you 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 Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much Valtrex, 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.

Drink plenty of fluids 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

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

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.

Some of these side effects (such as those marked * below) can only be found when your doctor does tests from time to time.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you. These are the most commonly reported side-effects:

- · headache
- nausea and other gastrointestinal discomfort (vomiting, diarrhoea, constipation, abdominal pain, indigestion)
- muscle aches or pains
- hallucinations
- · confusion, difficulty thinking
- · dizziness, drowsiness
- · anaemia*
- high blood pressure*

Allergic reactions to Valtrex are rare. However, if you think you are having an allergic reaction, tell your doctor immediately or go to your casualty department at your nearest hospital. Symptoms usually include some or all of the following:

- · wheezing
- swelling of the lips/mouth
- · difficulty in breathing
- · hay fever
- lumpy rash ("hives")
- fainting

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

- uncoordinated eye and muscle movements, and/or difficulty speaking
- decreased consciousness
- psychotic episodes
- · convulsions or seizures
- unusual bruising or bleeding, tiredness, dizziness, headaches, being short of breath when exercising. These may be signs of anaemia.

Some other side-effects of Valtrex tablets include:

- skin rash
- sensitivity of skin to UV light, such as development of a rash like sunburn even after short exposure to UV or sun light.
- kidney problems, which get better when Valtrex treatment is stopped.
- liver problems, which get better when Valtrex treatment is stopped.

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.

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 or if you have any questions.

After taking Valtrex tablets

Storage

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-anda 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°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 tablets, 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 white, film coated tablet, white to off-white core, biconvex, elongated, unscored engraved with "500" on one side and plain on the other. They are available in a pack size of 100 tablets.

Ingredients

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

Manufacturer

Arrow Pharma Pty Ltd 15-17 Chapel Street Cremorne VIC 3121

Further Information

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

Do not throw this leaflet away.

You may need to read it again.

This leaflet was revised in January 2018.

The information provided applies only to: Valtrex® tablets.

Valtrex 500mg tablets: AUST R 73918.