

# VALTREX(TM) 500mg Tablets for cytomegalovirus

*Valaciclovir*

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## Consumer Product Information

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### What is in this leaflet?

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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.

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### What Valtrex tablets are used for

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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.

Valtrex tablets are not addictive.

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

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### Before you take Valtrex tablets

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#### ***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, hayfever, 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.

#### ***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, cyclosporin 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. 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.

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## **How to take Valtrex tablets**

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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).

### **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.**

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## **While you are taking Valtrex tablets**

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### **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 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.**

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## **Side-Effects**

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**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.

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

The most commonly reported side-effects in patients taking Valtrex are:

- \* headache
- \* gastrointestinal discomfort (vomiting, nausea, diarrhoea, constipation, abdominal pain,

indigestion)

These should be reported to the doctor or pharmacist if they are severe or become troublesome.

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:

- \* Hallucinations
- \* Confusion
- \* Dizziness
- \* Drowsiness

**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

**Some rare side-effects of Valtrex tablets include:**

- \* unusual bruising or bleeding. Tell your doctor immediately if you notice any bruising or bleeding, as this may indicate that your blood is not clotting properly.
- \* sensitivity to UV light, such as development of a rash like sunburn even after short exposure to UV light. Talk to your doctor or pharmacist if you experience this.
- \* 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.**

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## After taking Valtrex tablets

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### 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 tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.**

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## Product description

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### 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 100 or 240 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.

## Manufacturer

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

## 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 prepared on 29 August 2008

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

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