GlaxoSmithKline

Package Leaflet: Information for the User

VALTREX® 250 mg film-coated tablets 500 mg film-coated tablets

valaciclovir

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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2 Before you take Valtrex
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1. What Valtrex is and what it is used for

Valtrex belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses called herpes simplex (HSV), varicella zoster (VZV) and cytomegalovirus (CMV).
Valtrex can be used to:

- treat shingles (in adults)
- treat HSV infections of the skin and genital herpes (in adults and adolescents over 12 years old). It is also used to help prevent these infections from returning.
- treat cold sores (in adults and adolescents over 12 years old)
- prevent infection with CMV after organ transplants (in adults and adolescents over 12 years old)
- treat and prevent HSV infections of the eye

2. Before you take Valtrex

Don't take Valtrex

- if you are allergic (hypersensitive) to valaciclovir or aciclovir or any of the other ingredients (listed in Section 6).
- Don't take Valtrex if this applies to you. If you are not sure, talk to your doctor or pharmacist before taking Valtrex.

Take special care with Valtrex

Check with your doctor or pharmacist before taking Valtrex if:

- **you have kidney problems**
- **you have liver problems**
- **you are over 65 years of age**
- **your immune system is weak**

If you are not sure if the above apply to you, talk to your doctor or pharmacist before taking Valtrex.

Prevent passing genital herpes on to others

If you are taking Valtrex to treat or prevent genital herpes, or you have had genital herpes in the past, you should still practice safe sex, including the use of condoms. This is important to prevent you passing the infection on to others. You should not have sex if you have genital sores or blisters.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

Tell your doctor or pharmacist if you are taking any other medicines that affect the kidneys. These include: aminoglycosides, organoplatinum compounds, iodinated contrast media, methotrexate, pentamidine, foscarnet, ciclosporin, tacrolimus, cimetidine and probenecid.

Always tell your doctor or pharmacist about other medicines if you are taking Valtrex for treatment of shingles or after having an organ transplant.

Pregnancy and breast-feeding

Valtrex is not usually recommended for use during pregnancy. If you are pregnant, or think you could be, or if you are planning to become pregnant, don't take Valtrex without checking with your doctor. Your doctor will weigh up the benefit to you against the risk to your baby of taking Valtrex while you're pregnant or breastfeeding.

Driving or using machines

Valtrex can cause side effects that affect your ability to drive.
➔Don't drive or use machines unless you are sure you're not affected.

3. How to take Valtrex

Always take Valtrex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dose that you should take will depend on why your doctor has prescribed Valtrex for you. Your doctor will discuss this with you.

Treatment of shingles

- The usual dose is 1000 mg (one 1000 mg tablet or two 500 mg tablets) three times a day.
- You should take Valtrex for seven days.

Treatment of cold sores

- The usual dose is 2000 mg (two 1000 mg tablets or four 500 mg tablets) twice a day.
- The second dose should be taken 12 hours (no sooner than 6 hours) after the first dose
- You should take Valtrex for one day (two doses) only.

Treatment of HSV infections of the skin and genital herpes

- The usual dose is 500 mg (one 500 mg tablet or two 250 mg tablets) twice a day.
- For the first infection you should take Valtrex for five days or for up to ten days if your doctor tells you to. For recurrent infection the duration of treatment is normally 3-5 days.

Helping to prevent HSV infections from returning after you have had them

- The usual dose is one 500 mg tablet once a day.
- Some people with frequent recurrences may benefit from taking one 250 mg tablet twice a day.
- You should take Valtrex until your doctor tells you to stop.

To stop you being infected with CMV (*Cytomegalovirus*)

- The usual dose is 2000 mg (two 1000 mg tablets or four 500 mg tablets) four times a day.
- You should take each dose about 6 hours apart.
- You will usually start taking Valtrex as soon as possible after your surgery.
- You should take Valtrex for around 90 days after your surgery, until your doctor tells you to stop.

Your doctor may adjust the dose of Valtrex if:

- you are over 65 years of age
- you have a weak immune system
- you have kidney problems.

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➔Talk to your doctor before taking Valtrex if any of the above apply.

Taking this medicine

- Take this medicine by mouth.
- Swallow the tablets whole with a drink of water.
- Take Valtrex at the same time each day.
- Take Valtrex according to instructions from your doctor or pharmacist.

People over 65 years of age or with kidney problems

It is very important while you are taking Valtrex that you drink water regularly during the day. This will help to reduce side effects that can affect the kidney or nervous system. Your doctor will closely monitor you for signs of these. Nervous system side effects might include feeling confused or agitated, or feeling unusually sleepy or drowsy.

If you take more Valtrex than you should

Valtrex is not usually harmful, unless you take too much over several days. If you take too many tablets you may feel sick, vomit, or be confused, agitated or unusually sleepy. Talk to your doctor or pharmacist if you take too much Valtrex. Take the medicine pack with you.

If you forget to take Valtrex

- If you forget to take Valtrex, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Don't take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, Valtrex can cause side effects in some people. The following side effects may happen with this medicine:

Conditions you need to look out for

- severe allergic reactions (*anaphylaxis*). These are rare in people taking Valtrex. Rapid development of symptoms including:
- flushing, itchy skin rash
- swelling of the lips, face, neck and throat, causing difficulty in breathing (*angiodema*)
- fall in blood pressure leading to collapse.

➔If you have an allergic reaction, stop taking Valtrex and see a doctor straight away.

Very Common (affects more than 1 in 10 people):

- headache

Common (affects up to 1 in 10 people)

- feeling sick
- dizziness
- vomiting
- diarrhoea
- skin reaction after exposure to sunlight (*photosensitivity*).
- rash

Uncommon (affects up to 1 in 100 people)

- feeling confused
- seeing or hearing things that aren't there (*hallucinations*)
- feeling very drowsy
- tremors
- feeling agitated

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of Valtrex a day. They usually get better when Valtrex is stopped or the dose reduced.

Other uncommon side effects:

- shortness of breath (*dyspnoea*)
- stomach discomfort
- rash, sometimes itchy, hive-like rash (*urticaria*)
- low back pain (kidney pain)
- blood in urine

Uncommon side effects that may show up in blood tests:

- reduction in the number of white blood cells (*leucopenia*)
- reduction in the number of *blood platelets* which are cells that help blood to clot (*thrombocytopenia*)
- increase in substances produced by the liver.

Rare (affects up to 1 in 1,000 people)

- unsteadiness when walking and lack of coordination (*ataxia*)
- slow, slurred speech (*dysarthria*)
- fits (convulsions)
- altered brain function (*encephalopathy*)
- unconsciousness (*coma*)
- confused or disturbed thoughts

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of Valtrex a day. They usually get better when Valtrex is stopped or the dose reduced.

Other rare side effects:

- kidney problems where you pass little or no urine.

5. How to store Valtrex

- Keep out of the reach and sight of children.
- Do not use Valtrex after the expiry date which is stated on the carton. The expiry date (Exp.) refers to the last day of that month.
- Store below 30°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help protect the environment.

6. Further information

What Valtrex contains

- The active substance is valaciclovir. Each tablet contains 250 mg or 500 mg of valaciclovir (as valaciclovir hydrochloride).

The other ingredients are:

Tablet core
Microcrystalline cellulose
Crospovidone
Povidone
Magnesium stearate
Colloidal silicon dioxide

Film coat
Hypromellose
Titanium dioxide
Macrogol
Polysorbate 80 (500 mg tablets only)
Carnauba wax

What Valtrex tablets look like and contents of the pack

Valtrex tablets are contained in polyvinyl chloride/aluminium foil blister packs.

Valtrex Tablets 250 mg are supplied to you in cartons containing 60 film-coated tablets. They are white and marked with "GX CE7" on one side.

Valtrex Tablets 500 mg are supplied in cartons containing 10, 30, 42, 90 or 112 film-coated tablets. They are white and marked with "GX CF1" on one side.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder
GlaxoSmithKline UK, Stockley Park West, Uxbridge, Middlesex, UB11 1BT

Manufacturer
Glaxo Wellcome, S.A. Avenida de Extremadura 3, 09400 Aranda de Duero, Burgos, Spain

Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	**Valtrex Tablets 250 mg** **Valtrex Tablets 500 mg**
Reference number	00003/0371

This is a service provided by the Royal National Institute of Blind People.

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