

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a physician's prescription only

Valtrex Tablets 500 mg

Each tablet contains 500 mg valaciclovir (as hydrochloride)

The list of additional ingredients is detailed in section 6.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Valtrex works by killing or stopping the growth of viruses called herpes simplex (HSV), varicella zoster (VZV) and cytomegalovirus (CMV).

Valtrex is intended to:

- Treat shingles in adults.
- Treat VZV infections of the eye (ophthalmic zoster) in adults with a weakened immune system.
- Treat HSV infections of the skin (e.g., cold sores) and genital herpes in adults and adolescents. It is also used to help prevent recurrence of these infections.
- Treat and prevent recurrence of HSV infections of the eye in adults and adolescents.
- Prevent infection with CMV after organ transplants in adults and adolescents.

Therapeutic group: Valtrex belongs to a group of medicines called antivirals.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

You are sensitive (allergic) to valaciclovir or aciclovir or to any of the additional ingredients contained in the medicine (as detailed in section 6).

Special warnings regarding use of the medicine

Before treatment with Valtrex, tell the physician if:

- You have kidney problems.
- You have liver problems.
- You are over 65 years of age.
- Your immune system is weak.

Take special care with Valtrex - Important Information:

Drug reaction with eosinophilia and systemic symptoms (also called DRESS) has been reported with the use of valaciclovir. DRESS appears initially as flu-like symptoms and a rash on the face, then a widespread rash with a high

fever, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

→ **If you develop a rash accompanied by fever and enlarged lymph nodes, stop taking valaciclovir and contact your physician or seek medical attention immediately.**

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 from passing the infection on to others. If you have genital sores or blisters, you should avoid having sex.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines, nutritional supplements and herbal medicines, tell the physician or pharmacist. Tell the physician or pharmacist if you are taking any other medicines that affect the kidneys. These include:

Aminoglycosides, organoplatinum compounds, iodinated contrast media, methotrexate, pentamidine, foscarnet, cimetidine, probenecid, ciclosporin, tacrolimus.

Pregnancy and breastfeeding

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

Driving and using machines

Valtrex can cause side effects that may affect your ability to drive (e.g., dizziness).

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions.

Check with the physician or pharmacist if you are uncertain regarding the preparation dosage and treatment regimen.

The dosage and treatment regimen will be determined by the physician only.

The usual dosage is generally:

Treatment of shingles (Herpes zoster) in adults

- The usual dosage is 1,000 mg (two 500 mg Valtrex tablets), three times a day.
- You should take Valtrex for seven days.

Treatment of cold sores in adults and adolescents (from age 12 and above)

- The usual dosage is 2,000 mg (four 500 mg Valtrex 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 in adults and adolescents (from age 12 and above)

- The usual dosage is one 500 mg Valtrex tablet, twice a day.
- For the first infection, you should take Valtrex for five days or for up to ten days, if your physician instructs you to. For recurrent infection, the duration of treatment is normally 3-5 days.

Helping to prevent HSV infections from returning in adults and adolescents (from age 12 and above)

- The usual dosage is one 500 mg Valtrex tablet, once a day.
- You should take Valtrex until your physician tells you to stop.

Treatment of CMV (Cytomegalovirus) infection in adults and adolescents (from age 12 and above)

- The usual dosage is 2,000 mg (four 500 mg Valtrex tablets), four times a day.
- You should take each dose separately, 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 physician tells you to stop.

Your physician may adjust the dosage of Valtrex if:

- You are over 65 years of age.
 - You have a weak immune system.
 - You have kidney problems.
- Talk to your physician before taking Valtrex if any of the above apply.

Do not exceed the recommended dose.

Taking this medicine:

- Take this medicine by mouth.
- Swallow the tablets whole with a drink of water.
- There is no information regarding crushing/halving/chewing.
- Take Valtrex at the same time each day.
- Take Valtrex according to the instructions from your physician 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 reduce side effects that may affect the kidney or nervous system. Your physician will closely monitor you for these signs. Nervous system side effects might include feeling confused or agitated, or feeling unusually sleepy or drowsy.

If you accidentally take a higher dosage

Valtrex is not usually harmful, unless you take too much over several days. If you take too many tablets, you may feel nauseous, vomit, get kidney problems, be confused, agitated, feel less aware, see things that do not exist, or become unconscious.

If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a physician or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forget to take the medicine

If you forgot to take Valtrex, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment regimen as recommended by the physician.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Valtrex may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Side effects requiring special attention

Conditions you need to look out for:

→ **Stop using Valtrex and seek medical attention immediately if any of the following symptoms occur:**

Severe allergic reactions (anaphylaxis). These are rare reactions 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 (angioedema)
- Fall in blood pressure leading to collapse

Skin rashes or redness. The adverse reaction of the skin may appear as rashes with or without blisters. Skin irritation, oedema (DRESS syndrome) and fever and flu-like symptoms may occur.

The following side effects may also happen with this medicine:

Very common side effects - effects occurring in more than one user in ten:

- Headache

Common side effects - effects occurring in 1-10 in 100 users:

- Nausea
- Dizziness
- Vomiting
- Diarrhea
- Skin reaction after exposure to sunlight (photosensitivity)
- Rash
- Itching

Uncommon side effects - effects occurring in 1-10 in 1,000 users:

- Feeling confused
- Seeing or hearing things that do not exist (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 dosages of 8 grams or more of Valtrex a day. These effects get better when Valtrex treatment is stopped or the dose reduced.

Other uncommon side effects:

- Shortness of breath (dyspnea)
- Stomach discomfort
- Rash, sometimes itchy, hive-like rash (urticaria)
- Lower back pain (kidney pain)
- Blood in urine (hematuria)

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 help the blood to clot (thrombocytopenia)
- Increase in levels of substances produced by the liver

Rare side effects - effects occurring in 1-10 in 10,000 users:

- Unsteadiness when walking and lack of coordination (ataxia)
- Slow, slurred speech (dysarthria)
- Fits (convulsions)
- Altered brain function (encephalopathy)
- Unconsciousness (coma)
- Confused or disturbed thoughts (delirium)

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

Other rare side effects:

- Kidney problems where you pass little or no urine

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Drug reaction with eosinophilia and systemic symptoms also known as DRESS or drug reaction hypersensitivity syndrome, which is characterised by widespread rash, high fever, liver enzyme elevations, abnormality in blood tests (eosinophilia), enlarged lymph nodes and possibly involvement of other body organs. See also section 2.
- An inflammation of the kidneys (tubulointerstitial nephritis)

If a side effect occurs, if one of the side effects worsens, or if you are suffering from a side effect not mentioned in the leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
<https://sideeffects.health.gov.il/>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 30°C.

6. ADDITIONAL INFORMATION

- **In addition to the active ingredient, the medicine also contains:**
Microcrystalline cellulose
Crospovidone
Povidone, K90
White Colour Concentrate YS-1-18043
(Hypromellose, Titanium dioxide, Polysorbate 80, Polyethylene Glycol 400)
Magnesium stearate
Colloidal Anhydrous Silica
Carnauba wax.
- **What the medicine looks like and the contents of the package:**
Valtrex Tablets are packaged in blister packs. Valtrex Tablets 500 mg are provided in cartons containing 2, 10, or 42 film-coated tablets. They are white and marked with “GX CF1” on one side.
Not all packages may be marketed.
- **Manufacturer:** GlaxoSmithKline Trading Services Limited, Dublin, Ireland.
- **License Holder:** GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 100-39-28426-00.

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