

PACKAGE LEAFLET: INFORMATION FOR THE USER

Valaciclovir Teva 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 you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Valaciclovir Teva is and what it is used for
2. Before you take Valaciclovir Teva
3. How to take Valaciclovir Teva
4. Possible side effects
5. How to store Valaciclovir Teva
6. Further information

1. WHAT VALACICLOVIR TEVA IS AND WHAT IT IS USED FOR

Valaciclovir Teva 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).

Valaciclovir Teva can be used to:

- treat shingles (in adults)
- treat HSV infections of the skin (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 VALACICLOVIR TEVA

Do NOT take Valaciclovir Teva

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

Take special care with Valaciclovir Teva

Check with your doctor or pharmacist before taking Valaciclovir Teva 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 Valaciclovir Teva.

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 Valaciclovir Teva for treatment of shingles or after having an organ transplant.

Pregnancy and breast-feeding

Valaciclovir Teva 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 Valaciclovir Teva without checking with your doctor. Your doctor will weigh up the benefit to you against the risk to your baby of taking Valaciclovir Teva while you're pregnant or breast-feeding.

Driving and using machines

Valaciclovir Teva 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 USE VALACICLOVIR TEVA

Always take Valaciclovir Teva 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 Valaciclovir Teva for you. Your doctor will discuss this with you.

Treatment of shingles

- The usual dose is 1000 mg (two 500 mg tablets) three times a day.
- You should take Valaciclovir Teva for seven days.

Treatment of cold sores

- The usual dose is 2000 mg (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 Valaciclovir Teva for one day (two doses) only.

Treatment of HSV infections of the skin

- The usual dose is 500 mg (one 500 mg tablet) twice a day.
- For the first infection you should take Valaciclovir Teva 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 half a 500 mg tablet twice a day.

- You should take Valaciclovir Teva until your doctor tells you to stop.

To stop you being infected with CMV (Cytomegalovirus)

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

Your doctor may adjust the dose of Valaciclovir Teva if:

- you are over 65 years of age
- you have a weak immune system
- you have kidney problems.
- Talk to your doctor before taking Valaciclovir Teva if any of the above apply.

Taking this medicine

- Take this medicine by mouth.
- Swallow the tablets whole with a drink of water.
- Take Valaciclovir Teva at the same time each day.
- Take Valaciclovir Teva 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 Valaciclovir Teva 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 Valaciclovir Teva than you should

Valaciclovir Teva 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 Valaciclovir Teva. Take the medicine pack with you.

If you forget to take Valaciclovir Teva

- If you forget to take Valaciclovir Teva, 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Valaciclovir Teva can cause side effects, although not everybody gets them. 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 Valaciclovir Teva. 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 Valaciclovir Teva and see a doctor straight away.

Very common (affects more than 1 user in 10):

- headache

Common (affects 1 to 10 users in 100)

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

Uncommon (affects 1 to 10 users in 1,000)

- 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 Valaciclovir Teva a day. They usually get better when Valaciclovir Teva 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)

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 1 to 10 users in 10,000)

- 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 Valaciclovir Teva a day. They usually get better when Valaciclovir Teva is stopped or the dose reduced.

Other rare side effects:

- kidney problems where you pass little or no urine

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE VALACICLOVIR TEVA

- Keep out of the reach and sight of children.
- Do not use Valaciclovir Teva after the expiry date which is stated on the carton. The expiry date refers to the last day of the 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. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Valaciclovir Teva contain

- The active substance is valaciclovir. Each tablet contains 500 mg valaciclovir (as valaciclovir hydrochloride dihydrate).
- The other ingredients are maize starch, croscarmellose sodium, sodium stearyl fumarate and cellulose powdered in the tablet core, and hypromellose (E464), titanium dioxide (E171), macrogol 400 and polysorbate 80 (E433) in the film-coating.

What Valaciclovir Teva look like and contents of the pack

- Valaciclovir Teva are white, biconvex, oblong, film-coated tablets, debossed “VL”, breakline and “D” on one side and plain on the other. The tablets can be divided into equal halves.
- Valaciclovir Teva are available in pack sizes of 1, 4, 6, 10, 24, 30, 42, 90 and 112 film-coated tablets. Hospital packs of 50 (50 x 1) film-coated tablets are also available.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva Pharma B.V.
Computerweg 10
3542 DR Utrecht
The Netherlands

Manufacturers

Pharmachemie B.V.
Swensweg 5, Postbus 552, 2003 RN Haarlem, The Netherlands

Teva Santé SA
Rue Bellocier, 89107 Sens, France

Teva Pharmaceutical Works Private Limited Company
Táncsics Mihály út 82, H-2100 Gödöllő, Hungary

Teva Pharmaceutical Works Private Limited Company
Pallagi út 13, 4042 Debrecen, Hungary

Teva Czech Industries s.r.o.
Ostravská 29, č.p. 305, 747 70 Opava –Komárov, Czech Republic

This medicinal product is authorised in the member states of the EEA under the following names

<i>France</i>	Valaciclovir Teva 500 mg, comprimé pellicule sécable
<i>Austria</i>	Valaciclovir TEVA 500 mg Filmtabletten
<i>Denmark</i>	Valaciclovir Teva
<i>Greece</i>	Valaciclovir/TEVA 500 mg Επικαλυμμένα με λεπτό υμένιο δισκία
<i>Spain</i>	Valaciclovir TEVA 500 mg comprimidos recubiertos con película EFG
<i>Finland</i>	Valaciclovir Teva 500 mg tabletti, kalvopäällysteinen
<i>Ireland</i>	Valaciclovir TEVA 500 mg Film-coated Tablets
<i>Italy</i>	Valaciclovir TEVA 500 mg compresse rivestite con film
<i>The Netherlands</i>	Valaciclovir 500 mg PCH, filmomhulde tabletten
<i>Norway</i>	Valaciclovir TEVA 500 mg tabletter, filmdrasjerte
<i>Portugal</i>	Valaciclovir Teva
<i>Sweden</i>	Valaciclovir Teva 500 mg filmdragerade tabletter
<i>Slovenia</i>	Valaciclovir Teva 500 mg filmsko obložene tablete
<i>Slovakia</i>	Valaciclovir – Teva 500 mg
<i>United Kingdom</i>	Valaciclovir 500 mg Film-Coated Tablets

This leaflet was last approved in 05/2015.