

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 because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Valaciclovir Teva is and what it is used for
2. What you need to know before you take Valaciclovir Teva
3. How to take Valaciclovir Teva
4. Possible side effects
5. How to store Valaciclovir Teva
6. Contents of the pack and other 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 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 that continue to come back (in adults and adolescents over 12 years old).

2. What you need to know before you take Valaciclovir Teva

Do not take Valaciclovir Teva

- if you are allergic to valaciclovir or aciclovir or any of the other ingredients of this medicine (listed in section 6).
- if you have ever developed an extended rash associated with fever, enlarged lymph nodes, increased levels of liver enzymes and/or eosinophilia (drug reaction with eosinophilia and systemic symptoms) after taking valaciclovir.

Do not take Valaciclovir Teva if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Valaciclovir Teva.

Warnings and precautions

Talk to 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.

Take special care with Valaciclovir Teva – Important Information:

Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported with the use of valaciclovir. DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, 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 associated with fever and enlarged lymph nodes, stop taking valaciclovir and contact your doctor or seek medical attention immediately.

Prevent passing genital herpes on to others

If you are taking Valaciclovir Teva 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.

Other medicines and Valaciclovir Teva

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. 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.

Valaciclovir Teva contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially "sodium-free".

3. How to take Valaciclovir Teva

Always take this medicine exactly as your doctor has told you. 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 and genital herpes

- 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.

Children below 12 years of age

Valaciclovir Teva is not recommended for use in children below 12 years of age.

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, get kidney problems, may be confused, agitated, feel less

aware, see things that aren't there, or become unconscious. 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Conditions you need to look out for :

Stop using Valaciclovir Teva and seek medical attention immediately if you notice any of the following symptoms:

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.

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 (may affect more than 1 in 10 people)

- headache

Common (may affect up to 1 in 10 people)

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

Uncommon (may affect 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 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)
- blood in urine (*haematuria*)

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 (may affect 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 (*delirium*)

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

Not known (cannot be estimated from the available data)

- drug reaction with eosinophilia and systemic symptoms also known as DRESS or drug hypersensitivity syndrome, which is characterised by widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and possibly other body organs involvement. See also section 2.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance Website: www.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 this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.
- Store below 30°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Valaciclovir Teva contains

- 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 looks 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 doses.
- Valaciclovir Teva are available in pack sizes of 1, 4, 6, 8, 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.
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Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Valaciclovir Teva 500 mg filmovertrukne tabletter
France	VALACICLOVIR TEVA 500 mg, comprimé pelliculé sécable
Spain	Valaciclovir TEVA 500 mg comprimidos recubiertos con película EFG
Finland	Valaciclovir ratiopharm 500 mg tabletti, kalvopäällysteinen
Ireland	Valaciclovir Teva 500 mg Film-coated Tablets
The Netherlands	Valaciclovir 500 mg PCH, filmomhulde tabletten

This leaflet was last approved in August 2021.