Package leaflet: Information for the patient

Valaciclovir 500 mg film-coated tablets

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

In this leaflet:

1. What Valaciclovir is and what it is used for
2. What you need to know before you take Valaciclovir
3. How to take Valaciclovir
4. Possible side effects
5. How to store Valaciclovir
6. Contents of the pack and other information

1. What Valaciclovir is and what it is used for

Valaciclovir contains the active substance valaciclovir hydrochloride, hydrate. Valaciclovir 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 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 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

Do not take Valaciclovir:
- 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 node, increased levels of liver enzymes and/or eosinophilia (drug reaction with eosinophilia and systemic symptoms) after taking valaciclovir.

If you are not sure, talk to your doctor or pharmacist before taking Valaciclovir.

Warnings and precautions

Talk to your doctor or pharmacist before taking Valaciclovir if:
- you have kidney problems
- you have liver problems
- you are over 65 years of age
- your immune system is weak

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.

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

Prevent passing genital herpes on to others
If you are taking Valaciclovir to treat 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.

Children under 12 years of age
This medicine is not recommended for children under 12 years of age.

Other medicines and Valaciclovir
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 for treatment of shingles or after having an organ transplant.

Pregnancy and breast-feeding
Valaciclovir is not usually recommended for use during pregnancy. If you are pregnant, or think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking Valaciclovir. Your doctor will weigh up the benefit to you against the risk to your baby of taking Valaciclovir while you are pregnant or breastfeeding.

Driving and using machines
Valaciclovir may cause side effects that affect your ability to drive. Do not drive or use machines unless you are sure you are not affected.

3. How to take Valaciclovir

Always take this medicine exactly as your doctor or pharmacist 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 for you. Your doctor will discuss this with you.

Treatment of shingles:
- The recommended dose is 1000 mg (two 500 mg tablets) three times a day.
- You should take Valaciclovir for seven days.

Treatment of cold sores:
- The recommended 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 for one day (two doses) only.

Treatment of HSV infections of the skin and genital herpes:
- The recommended dose is 500 mg (one 500 mg tablet) twice a day.

- For the first infection you should take Valaciclovir 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 recommended 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. For doses less than 500 mg, Valaciclovir 500 mg Film-coated Tablets are not suitable. Lower strengths of other valaciclovir medicinal products are available. Your doctor will advise you accordingly.
- You should take Valaciclovir until your doctor tells you to stop.

To stop you being infected with CMV (Cytomegalovirus):

- The recommended 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 as soon as possible after your surgery.
- You should take Valaciclovir for around 90 days after your surgery, until your doctor tells you to stop.

Children under 12 years of age

Valaciclovir is not recommended for use in children below the age of 12 years due to insufficient data on safety and efficacy.

Your doctor may adjust the dose of Valaciclovir 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 if any of the above apply.

Method of administration:

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

Valaciclovir 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, see, feel or hear things that are not there (hallucinations), have kidney problems where you pass little or no urine or lose consciousness (coma). Talk to your doctor or pharmacist if you take too much Valaciclovir. Take the medicine pack with you.

If you forget to take Valaciclovir:

- If you forget to take Valaciclovir, 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.

If you stop taking Valaciclovir

Do not stop taking this medicine without consulting your doctor.

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

4. Possible side effects

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

The side effects usually occur in the beginning of treatment and become milder or stop altogether within a few weeks. Sometimes it is difficult to tell the difference between symptoms of an illness and side effects.

If you think you may have any of the following side effects, stop taking this medicine and contact your doctor or go to your nearest hospital emergency room immediately:

Rare (may affect up to 1 in 1,000 people):

- severe allergic reactions (anaphylaxis). 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.
- kidney problems where you pass little or no urine
- fits (convulsions)
- altered brain function (encephalopathy)
- unconsciousness (coma)
- confused or disturbed thoughts (psychoses).

Not known (cannot be estimated from 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.
- an inflammation of the kidneys (tubulointerstitial nephritis).

Other side effects include:

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.

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 a day. They usually get better when Valaciclovir 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 the 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 (may affect up to 1 in 1,000 people):
- unsteadiness when walking and lack of coordination (ataxia)
- slow, slurred speech (dysarthria)

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

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 Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Valaciclovir

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 foil after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 protect the environment.

6. Contents of the pack and other information

What Valaciclovir contains

The active substance is valaciclovir hydrochloride, hydrate. Each tablet contains Valaciclovir hydrochloride, hydrate equivalent to 500 mg of valaciclovir.

The other ingredients in the tablet core are: cellulose, microcrystalline; crospovidone; povidone and magnesium stearate.
The ingredients in the coating are: titanium dioxide (E171); macrogol 400; polysorbate 80 (E433) and hypromellose (E464).

What Valaciclovir looks like and contents of the pack

Valaciclovir are white to off-white, capsule-shaped, biconvex film-coated tablets with "VC 500" on one side and "G" on the other side.

Valaciclovir is available in blister strips in packages of 10, 21, 24, 30, 42, 60, 90, 100 and 112 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Viatris,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

Manufacturer:
Mylan Hungary Kft,
H-2900 Komarom,
Mylan utca 1,
Hungary.

This leaflet was last revised in September 2026.