

Valaciclovir 500mg 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 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.

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1 What Valaciclovir tablets are and what they are used for

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 and prevent HSV infections of the eye.

2 What you need to know before you take Valaciclovir tablets

Do not take Valaciclovir tablets

- if you are **allergic** to valaciclovir or aciclovir or any of the other ingredients of this medicine (listed in Section 6).
- Do not take Valaciclovir tablets if this applies to you. If you are not sure, talk to your doctor or pharmacist before taking Valaciclovir tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Valaciclovir tablets 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.

Prevent passing genital herpes on to others

If you are taking Valaciclovir tablets 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 tablets

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 tablets 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 could be, or if you are planning to become pregnant, don't take Valaciclovir tablets without checking with your doctor. Your doctor will weigh up the benefit to you against the risk to your baby of taking Valaciclovir tablets while you're pregnant or breastfeeding.

Driving and using machines

Valaciclovir 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 Valaciclovir tablets

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 tablets for you. Your doctor will discuss this with you.

• Treatment of shingles

The usual dose is 1000mg three times a day. You should take Valaciclovir tablets for seven days.

• Treatment of cold sores

The usual dose is 2000mg 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 usual dose is 500mg twice a day. For the first infection you should take Valaciclovir tablets 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 250mg twice a day. Taking one 250mg tablet twice a day may give benefit to some people with frequent recurrences (instead of one 500mg tablet once a day). You should take Valaciclovir tablets until your doctor tells you to stop.

• To stop you being infected with CMV (Cytomegalovirus)

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

Your doctor may adjust the dose of valaciclovir tablets 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 tablets 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 tablets at the same time each day. Take Valaciclovir tablets 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 tablets 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 tablets are not recommended for use in children below 12 years of age.

If you take more valaciclovir tablets 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. Talk to your doctor or pharmacist if you take too much valaciclovir. Take the medicine pack with you.

If you forget to take valaciclovir tablets
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. Do not take a double dose to make up for a forgotten dose.

4 Possible side effects

Like all medicines, this medicine 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 tablets. 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. If you have an allergic reaction, stop taking valaciclovir tablets 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 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 (*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 (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
• disorientation and confusion often accompanied by hallucinations (*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 a day. They usually get better when valaciclovir 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the internet at www.mhra.gov.uk/yellowcard. Alternatively you can call Freephone 0800 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Valaciclovir tablets

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 label, carton or bottle after EXP. The expiry date refers to the last day of that month. Do not store above 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 protect the environment.

6 Contents of the pack and other information

What Valaciclovir tablets contain

- The active substance is valaciclovir. Each tablet contains 500mg valaciclovir (as valaciclovir hydrochloride monohydrate).
- The other ingredients are *tablet core*: cellulose microcrystalline, povidone, magnesium stearate, *tablet coating (Opadry White Y-5-7068)*: hypromellose, hydroxypropyl cellulose, titanium dioxide (E171), macrogol 400, hypromellose.

What Valaciclovir tablets look like and contents of the pack

Valaciclovir tablets are oval, white, biconvex and film-coated with the following size and markings:
500mg tablets: 17.6 x 8.8mm with VC2 on one side

PVC/aluminium blister
Pack sizes (Blisters): 10, 20, 21, 24, 30, 42, 60, 90 film-coated tablets

HDPE containers with tamper evident LDPE cap
Pack sizes (Bottles): 10, 30, 100, 250 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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