Read all of this leaflet carefully before you start taking this medicine as 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 signs of illness seem 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 tablets are and what they are used for
2. What you need to know before you take Valaciclovir tablets
3. How to take Valaciclovir tablets
4. Contents of the pack and other information
5. What to do if you think this medicine is not working for you

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 simplexes (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.

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).
- if you have kidney problems.
- if you have liver problems.
- if you are over 65 years of age.
- if 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 tablets.

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, icosindan contrast media, methotrexate, pentamidine, foscarnet, ciclosporin, tacrolimus, cinididine, 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 breastfeeding

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.

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.
- you have liver problems.
- you have problems affecting the kidneys.

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.
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.
- Common (affects 1 to 10 users in 100):
  - feeling sick
  - 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
  - feeling agitated

These nervous system side effects usually occur in people with kidney problems where you pass little or no urine. 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):
- nightmares when waking and lack of coordination (ataxia)
- slow, slurred speech (dysarthria)
- fits (convulsions)
- altered brain function (encephalopathy)
- uncoordinated movements (ataxia)
- 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 0808 100 3352 (available from 10 am to 2 pm. Mondays to Fridays) or fill in a paper form available from your local pharmacy. By reporting side effects you can help provide further information on the safety of this medicine.

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 this date, do not use the medicine even if it looks or smells good. 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.

Contents of the pack and other information

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, lactose monohydrate, hydroxypropyl cellulose, titanium dioxide (E171), magnesium stearate, tablet coating (Opadry White Y-5-7068): hypromellose, hydroxypropyl cellulose, titanium dioxide (E171), macrogol 400, hypromellose.

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
- P/C 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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