

PACKAGE LEAFLET: INFORMATION FOR THE USER

Valaciclovir 500mg Film Coated Tablets

Valaciclovir

Read all of this leaflet carefully before you start using 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Valaciclovir 500mg film coated tablet is and what it is used for
2. Before you take Valaciclovir 500mg film coated tablets
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1. WHAT Valaciclovir 500mg film coated tablets IS AND WHAT IT IS USED FOR

Valaciclovir 500mg film coated tablets belongs to the group of antivirals. The active ingredient valaciclovir is transformed into aciclovir in the body, which is active against various viral infections.

This medicine is used

- for herpes simplex viral infections of the skin and mucous membranes, including initial and recurrent genital herpes. The medicine can be used for preventative treatment against recurrent infections.
- for shingles (herpes zoster) infection.
- as preventive treatment for cytomegalovirus infection following renal transplantation.

2. BEFORE YOU TAKE Valaciclovir 500mg film coated tablets

Do not take Valaciclovir 500mg film coated tablets

- if you are allergic (hypersensitive) to valaciclovir, aciclovir or any of the other ingredients of Valaciclovir 500mg film coated tablets.

Take special care with Valaciclovir 500mg film coated tablets

- if you have a kidney disease, dose adjustment could be necessary.
- if you have a liver disease and require high doses of the medicine.

Care should be taken to ensure adequate fluid intake in patients who are at risk of dehydration, particularly the elderly and patients with impaired kidney function.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Valaciclovir 500mg film

coated tablets could affect the efficacy of other medicines and other medicines could affect the efficacy of Valaciclovir 500mg film coated tablets.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- probenecid, used to treat gout
- cimetidine, used to treat stomach ulcers
- tacrolimus, ciclosporin or mycophenolate mofetil, used to stop your body rejecting transplanted organs.

Taking Valaciclovir 500mg film coated tablets with food and drink

Swallow the tablets with water. They can be taken with or without food.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine. Experience of use of this medicine in pregnant women is limited.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. The medicine is secreted into breast-milk, but effects on the child are considered unlikely.

Driving and using machines

No known effect on the ability to drive or use machines.

While evaluating your ability to drive or use machines you should however bear in mind the possible side effects of Valaciclovir 500mg film coated tablets that can impair your concentration (see section 4).

Important information about some of the ingredients of Valaciclovir 500mg film coated tablets

This medicine contains a small amount of lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE Valaciclovir 500mg film coated tablets

Always take the medicine exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

The usual dose for herpes simplex infections is one 500 mg tablet twice daily for 5 days. For recurrent infections, treatment should be maintained for 5 days. For initial episodes, which can be more severe, treatment may have to be extended to 10 days. Dosing should begin as early as possible. For recurrent episodes of herpes simplex, this should ideally be during the prodromal period or immediately the first signs or symptoms appear.

The usual dose for shingles (herpes zoster) is two 500 mg tablets (1000 mg) three times a day for one week. The treatment should be started as soon as possible after the symptoms appear, preferably within 72 hours.

The usual dose for prevention of cytomegalovirus infections following organ transplantation is four tablets (2 g) four times a day.

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

If you take a larger dose than recommended

Consult a doctor if you take a larger dose than recommended

If you forget to take Valaciclovir 500mg film coated tablets

If you forget to take a dose, take it as soon as you remember and then the next one at the usual time. Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Valaciclovir 500mg film coated tablets can cause side effects, although not everybody gets them.

Common: affects 1 to 10 users in 100

Headache, nausea

Uncommon: affects 1 to 10 users in 1,000

Dyspnoea, rash, including photosensitivity reactions

Rare: affects 1 to 10 users in 10,000

Dizziness, confusion, hallucinations, impaired consciousness, abdominal discomfort, vomiting, diarrhoea, pruritus, impaired kidney function

Very rare: affects less than 1 user in 10,000

Anaphylactic reactions, thrombocytopenia, leukopenia, tremor, spontaneous muscle movements (ataxia), speaking disorders (dysarthria), convulsions, brain disorder (encephalopathy), coma, urticaria, angioedema, acute kidney failure, transient elevation of liver function test results.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE Valaciclovir 500mg film coated tablets

Keep out of the reach and sight of children.

Store below 30°C.

Do not use Valaciclovir 500mg film coated tablets after the expiry date which is stated on the carton.

The expiry date refers to the last day of that month.

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 is in Valaciclovir 500mg film coated tablets?

The active ingredient is valaciclovir (as valaciclovir hydrochloride)

Each film-coated tablet contains 500 mg of valaciclovir (as valaciclovir hydrochloride)

The other ingredients are: Calcium hydrogen phosphate, sodium starch glycolate, hydroxypropylcellulose, talcum, magnesium stearate, hypromellose, lactose, titanium dioxide (E171), macrogol 4000.

What Valaciclovir 500mg film coated tablets look like and contents of the pack

Valaciclovir 500mg film coated tablets are white, oblong, biconvex film coated tablets

The film-coated tablets are packed in blister packs (PVC/PE/PVDC/aluminium).

Pack sizes: 10 tablets, 40 tablets, 42 tablets.

Not all pack sizes may be marketed.

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For any information about this medicine, please contact the Marketing Authorisation Holder

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