

VALOVIR TABLET

Valaciclovir hydrochloride (500 mg)

What is in this leaflet

1. What VALOVIR is used for
2. How VALOVIR works
3. Before you use VALOVIR
4. How to use VALOVIR
5. While you are using it
6. Side effects
7. Storage and Disposal of VALOVIR
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What VALOVIR is used for

VALOVIR can be used to:

- treat shingles (in adults)
- treat herpes simplex viruses (HSV) infections of the skin and genital herpes. It is also used to help prevent these infections from returning.
- prevent lesion development when taken at the first signs and symptoms of an HSV recurrence
- reduce transmission of genital herpes when taken as suppressive therapy and combined with safer sex practices (such as condom).

How VALOVIR works

VALOVIR belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses called herpes simplex (HSV).

Before you use VALOVIR

-When you must not use it

Do not take VALOVIR

- if you are allergic (hypersensitive) to valaciclovir or aciclovir or any of the other ingredients.

Do not take VALOVIR if this applies to you. If you are not sure, talk to your doctor or pharmacist before taking VALOVIR.

Pregnancy and breast-feeding

VALOVIR 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, do not take VALOVIR without checking with your doctor. Your doctor will weigh up the benefit to you against the risk to your baby of taking VALOVIR while you are pregnant or breastfeeding.

-Before you start to use it

Check with your doctor or pharmacist before taking VALOVIR if:

- you have kidney problems
- you have liver problems
- you are elderly
- your immune system is weak

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

-Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken 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:

- Cyclosporine (used to prevent rejection of organ transplant)
- Tacrolimus (used to prevent rejection of organ transplant)
- cimetidine (used to treat and prevent heartburn from acid indigestion in the stomach)
- probenecid (used to treat gout)

Always tell your doctor or pharmacist about other medicines if you are taking VALOVIR for treatment of shingles or after having an organ transplant.

How to use VALOVIR

-How much to use

Always take VALOVIR exactly as your doctor has told you. You should 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 VALOVIR 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 VALOVIR for seven days.

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 VALOVIR for up to ten days if your doctor tells you to.
- For recurrent infection the duration of treatment is normally 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 (eg 10 or more per year) may gain additional benefit from the daily dose of 500 mg being taken as a divided dose (250 mg twice daily)
- For immunocompromised adult patients the dose is 500 mg twice daily

Reduce the transmission of genital herpes

- For immunocompetent heterosexual adult with 9 or fewer recurrences per year, the dose for the infected partner is 500 mg once daily.

VALOVIR is not recommended for children.

VALOVIR TABLET

Valaciclovir hydrochloride (500 mg)

Your doctor may adjust the dose of VALOVIR if:

- you are elderly
- you have a weak immune system
- you have kidney problems.

Talk to your doctor before taking VALOVIR if any of the above apply.

-When to use it

Take this medicine by mouth. Swallow the tablets whole with a drink of water. Take VALOVIR at the same time each day. Take VALOVIR according to instructions from your doctor or pharmacist.

-How long to use it

Continue taking VALOVIR for as long as your doctor recommends.

-If you forget to use it

If you forget to take VALOVIR, 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 use too much (overdose)

VALOVIR is not usually harmful, unless you take too much over several days. If you take too many tablets you may experience kidney and neurological problems which includes stomach discomfort, vomiting, confusion, agitation, decreased in consciousness, hallucination or become unconscious. Talk to your doctor or pharmacist if you take too much VALOVIR. Take the medicine pack with you.

While you are using VALOVIR

-Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

-Things you must not do

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.

-Things to be careful of

Elderly and people with kidney problems:

It is very important while you are taking VALOVIR 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.

Driving or using machines VALOVIR can cause side effects that affect your ability to drive. Do not drive or use machines unless you are sure you're not affected.

Prevent passing genital herpes on to others.

If you are taking VALOVIR 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.

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:

Common (may affect up to 1 in 10 people):

- Headache
- Stomach discomfort (nausea)

Uncommon (may affect up to 1 in 100 people):

- Shortness of breath (dyspnoea)
- Skin reaction after exposure to sunlight (photosensitivity).

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

- Stomach discomfort
- Vomiting
- Diarrhoea
- Itching (pruritus)
- Kidney problems where you pass little or no urine
- Dizziness
- Confusion
- Seeing or hearing things that aren't there (hallucinations)
- Decreased consciousness

Very rare side effects (may affect up to 1 in 10,000 people):

- 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)
- Anaphylaxis
- Agitation
- Tremor
- Unsteadiness when walking and lack of coordination (ataxia)
- Slow, slurred speech (dysarthria)
- Fits (convulsions)
- Altered brain function (encephalopathy)
- Unconsciousness (coma)
- Reversible increases in liver function tests (hepatitis)
- Rash, sometimes itchy, hive- like rash (urticaria)
- Angioedema (swelling beneath the skin due to fluid leakage from blood vessels)
- Acute kidney failure
- Low back pain (kidney pain)

Leucopenia is mainly reported in immunocompromised patients.

VALOVIR TABLET

Valaciclovir hydrochloride (500 mg)

Drug reaction with eosinophilia and systemic symptoms (DRESS) (serious skin reaction that may affect one or more organs): fever, severe rash, peeling skin, swelling of the face, swollen lymph glands, flu-like feeling, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feel thirsty, urinating less often, less urine.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of VALOVIR

-Storage

- 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. The expiry date (Exp.) refers to the last day of that month.

- Store below 30°C.

-Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

Product Description

-What it looks like

white to off-white, caplet shaped tablets, debossed with 'V' on one side and '500' on other side.

-Ingredients:

-Active ingredients:

Valaciclovir hydrochloride

-Inactive ingredients:

Microcrystalline cellulose, Crospovidone, Povidone, Magnesium stearate, Film coat, Opadry white and Purified Water.

-MAL number:

MAL13030002AZ

Manufacturer

Hetero Drugs Limited
Unit III, 22-110, I.D.A. Jeedimetla,
Hyderabad - 500 055, Telangana,
India.

Product Registration Holder

Camber Laboratories Sdn. Bhd.
Unit E-13A-02, Menara SUEZCAP 2,
No.2, KL Gateway, Jalan Kerinchi,
Gerbang Kerinchi Lestari,
59200 Kuala Lumpur, Malaysia

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