

PACKAGE LEAFLET: INFORMATION FOR THE USER

HERNOVIR

200 mg tablets

ACICLOVIR

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What HERNOVIR TABLETS are and what they are used for
2. What you need to know before you take HERNOVIR TABLETS
3. How to take HERNOVIR TABLETS
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1. WHAT HERNOVIR TABLETS ARE AND WHAT THEY ARE USED FOR

Hernovir Tablets contain aciclovir, one of a group of medicines called antivirals. It works by killing or stopping the growth of viruses.

Aciclovir can be used to

- treat or prevent herpes simplex infections of the skin and mucous membranes e.g. cold sores and genital herpes (excluding herpes simplex virus infection in neonates and severe herpes simplex virus infections in children whose immune system is not working properly)
- prevent herpes simplex infections in patients whose immune system is not working properly
- treat chickenpox (varicella) and shingles (herpes zoster) infections.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE HERNOVIR TABLETS

Do not take HERNOVIR TABLETS

- if you are allergic to aciclovir or valaciclovir or any of the other ingredients of this medicine.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking HERNOVIR TABLETS

- if you have kidney problems
- if you are elderly
- if you have previously had treatment with aciclovir, which did not work.

Please inform your doctor or pharmacist, if you are not sure if the above applies to you.

Children

Hernovir Tablets can be used mainly for the treatment of non-severe skin and mucous membranes herpes simplex virus (HSV) infections. Your child's doctor will recommend IV aciclovir for the treatment of neonatal HSV and severe HSV infection, if your child's immune system is not working properly.

Other medicines and Hernovir Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- Probenecid (used for treating gout as well as used along with other antibiotics for treating severe infections)
- Cimetidine (used for healing peptic ulcer)
- Mycophenolate mofetil (medicine used in transplant patients which suppresses immunity).

Hernovir Tablets with food and drink

Hernovir Tablets can be taken without regard to meals. If you are taking high doses of aciclovir or if you are elderly or you have problems with your kidneys, you should drink plenty of water to prevent the risk of kidney damage.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines There is no available information on the effect of aciclovir on driving and using machines. Some side effects such as drowsiness or sleepiness and dizziness may impair your ability to concentrate and react. Make sure you know how you react to this medicine before you drive or use machines.

3.HOW TO TAKE HERNOVIR

TABLETS

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 tablets may be dissolved in 50 ml of water before taking or swallowed with a little water if you prefer.

Dosage

The recommended doses are as follows, but your doctor may decide to adjust the dose and the treatment period according to your condition, especially if your body's natural ability to fight infection is weakened.

If you have a new outbreak of herpes virus infection while you are taking Hernovir tablets, tell your doctor.

Adults:

For treatment of active herpes simplex infection

Take one Hernovir tablet, five times a day, every four hours, except during the night. Start treatment as soon as signs of infection are present. Treatment is usually for 5 days. This may be longer when infection is severe.

In patients with very weak defence reactions, e.g. after a bone marrow transplant or patients who have poor absorption, the dose can be increased to 400 mg or alternatively you may be given an injection (into a vein).

To prevent herpes simplex infections from returning

Take one HERNOVIR tablet, four times a day, every six hours Or

Take two HERNOVIR tablets, twice daily, every 12 hours. You should not use this medicine for longer than six to twelve months at a time without discussing with your doctor whether you still need to take it.

Prevention of herpes simplex infection in patients with weakened body defence

Take one HERNOVIR tablet, four times a day, every six hours.

In patients with very weak defence reactions, e.g. after a bone marrow transplant or patients who have poor absorption, the dose can be increased to 400 mg. Treatment should continue as long as there is a risk of infection.

Alternatively, you may be given an injection (into a vein).

Treatment of chicken pox (varicella) and shingles (herpes zoster)

The usual dose is 800 mg taken five times a day, every four hours except during the night. Start treatment as soon as the rash or other symptoms appear. Treatment should be continued for seven days.

Patients with a very weak defence reactions, e.g. after a bone marrow transplant or patients who have poor absorption, may be given an injection (into a vein).

Use in children and adolescents For treatment of active herpes simplex infections and prevention of herpes simplex infections in patients with weakened body defence Children aged two years and older may receive the adult doses described above. Children below the age of two years should be given half the dose.

Treatment of chicken pox (varicella infection)

6 years and over: 800 mg aciclovir four times daily

2-5 years: 400 mg aciclovir four times daily

Under 2 years: 200 mg aciclovir four times daily

Treatment should continue for five days.

Elderly:

Doses should be as for adults unless kidney problems are present. Doses should then be reduced and calculated with reference to kidney function. Elderly patients taking high doses of aciclovir orally should ensure sufficient fluid intake.

Patients with kidney problems: Caution should be taken if you have kidney problems and are taking aciclovir.

For Treatment of herpes simplex infection

If kidney function is severely impaired, the dose of aciclovir should not exceed 200 mg, twice daily, every twelve hours.

For Treatment of herpes zoster infection

If kidney function is severely impaired, the dose of aciclovir should not exceed 800 mg, twice daily, every twelve hours.

If kidney function is moderately impaired, the dose of aciclovir should not exceed 800 mg, three times daily, every 8 hours.

If you have impaired kidney function, you must make sure that your intake of fluids is sufficient.

If you have the impression that the effect of HERNOVIR Tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more HERNOVIR Tablets than you should, go to the nearest hospital casualty department or contact your doctor immediately. Take this leaflet or the blister pack with you so your doctor will know what you have taken. Signs of an overdose include feeling or being sick and headache and confusion.

If you forget to take HERNOVIR Tablets, take one as soon as you can, then go on as before. If you miss several doses, tell your Doctor. Do not take a double dose to make up for a forgotten dose. Try to space the doses as evenly as possible through the day.

If you stop taking HERNOVIR Tablets Take your tablets as directed and for as long as directed; do not stop them, even if you feel better, as symptoms may return.

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

4. POSSIBLE SIDE EFFECTS

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

Serious side effects

If any of the following happen, stop taking Hernovir Tablets and tell your doctor immediately or go to the casualty department at your nearest hospital.

Severe allergic reaction such as rash, itching or hives on your skin, swelling of your face, lips, tongue or other parts of your body. These are very serious side effects and are rare (may affect up to 1 in 1,000 people).

Other side effects

Common (may affect up to 1 in 10 people)

- skin rashes including increased sensitivity of the skin to sun (photosensitivity)
- itching
- fever
- headache
- feeling sick (nausea), being sick (vomiting)
- diarrhoea, pain in the abdomen
- dizziness
- feeling very tired.

Uncommon (may affect up to 1 in 100 people)

- hive-like rash, hair loss

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

- difficulty in breathing.

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

- changes in the number of different type of blood cells may cause increased bruising, sore throat, nose bleeds, infections, excessive tiredness, breathlessness on exertion, or abnormal paleness of the skin
- feeling agitated or confused
- shaking or tremors
- hallucinations (seeing or hearing things that are not real)
- fits (convulsions)
- feeling unusually sleepy or drowsy
- unsteadiness when walking and lack of coordination
- difficulty speaking
- mental illness with strange or disturbing thoughts or moods
- unconsciousness (coma)
- paralysis of part or all of your body, disturbance of behaviour, speech and eye movements, stiff neck and sensitivity to light.

The above side effects are temporary and usually occur in patients with kidney problems.

- inflammation of the liver, yellowing of your skin and whites of your eyes (jaundice)
- kidney problems where you pass little or no urine, kidney pain which may be associated with kidney failure or crystalluria (presence of crystals in the urine).

Laboratory tests

Rarely, tests have shown increases in blood urea and creatinine level and temporary changes in liver function and components of the blood like bilirubin.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5.HOW TO STORE HERNOVIR 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 blister and the carton. The expiry date refers to the last day of that month.
- 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.

***This leaflet was last revised in
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