

Package leaflet: Information for the user
Aciclovir SUN 400 mg 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take Aciclovir 400 mg Tablets
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1. What Aciclovir 400 mg Tablets are and what they are used for

Aciclovir 400 mg Tablets contain a medicine called aciclovir. This belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses.

Aciclovir can be used to

- treat chickenpox and shingles
- treat cold sores, genital herpes and other herpes simplex infections
- stop these problems returning after you have had them
- stop these problems in people whose immune system works less well, which means their bodies are less able to fight infections

2. What you need to know before you take Aciclovir 400 mg Tablets

Do not take Aciclovir 400 mg Tablets:

- if you are allergic to aciclovir or valaciclovir or any of the other ingredients of this medicine (listed in section 6).

Do not take Aciclovir 400 mg Tablets if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Aciclovir 400 mg Tablets.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Aciclovir 400 mg Tablets

- if you have kidney problems
- if you are over 65 years of age

If you are not sure if the above apply to you, talk to your doctor or pharmacist before taking Aciclovir 400 mg Tablets.

It is important that you drink plenty of water while taking Aciclovir 400 mg Tablets

Children

Aciclovir 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 Aciclovir 400 mg 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.

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
- mycophenolate mofetil, used to stop your body rejecting transplanted organs.

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

Some side effects such as feeling drowsy or sleepy may impair your ability to concentrate and react. Make sure you are not affected before you drive or operate machinery.

3. How to take Aciclovir 400 mg 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.

Taking this medicine

- Take this medicine by mouth
- Dissolve the tablet in a glass of water and stir before drinking
- If you prefer, the tablet can also be swallowed whole with a little water.
- Start to take Aciclovir 400 mg Tablets as soon as possible.

The dose that you should take will depend on what you have been given Aciclovir 400 mg Tablets for. Your doctor will discuss this with you. A 200 mg tablet is also available.

Treatment of chickenpox and shingles

- The usual dose is two 400 mg taken five times a day
 - You should space each dose by 4 hours
- Suggested times are: **7am, 11am, 3pm, 7pm and 11pm**
- You should take Aciclovir 400 mg Tablets for seven days.

Treatment of cold sores and genital herpes

- The usual dose is one 200 mg tablet taken five times a day
 - You should space each dose by 4 hours
- Suggested times are: **7am, 11am, 3pm, 7pm and 11pm**
- You should take Aciclovir 400 mg Tablets for five days, or longer if your doctor tells you to.

Stopping these problems returning after you have had them

- The usual dose is one 200 mg tablet taken four times a day
- You should try to space each dose by 6 hours

- You should take Aciclovir 400 mg Tablets until your doctor tells you to stop.

Stopping these problems in people whose immune systems work less well and whose bodies are less able to fight infections

- The usual dose is one 200 mg tablet taken four times a day
- You should try to space each dose by 6 hours
- You should take Aciclovir 400 mg Tablets until your doctor tells you to stop.

Your doctor may adjust the dose of Aciclovir 400 mg Tablets if:

- it is for a child
- you are over 65 years of age
- you have kidney problems. If you have kidney problems, it is important to drink plenty of water while you are being treated with Aciclovir 400 mg Tablets

Talk to your doctor before taking Aciclovir 400 mg Tablets if any of the above apply.

If you take more Aciclovir Tablets than you should

Aciclovir 400 mg Tablets is not usually harmful, unless you take too much over several days. Talk to your doctor or pharmacist if you take too much Aciclovir 400 mg Tablets. Take the medicine pack with you.

If you forget to take Aciclovir Tablets

- If you forget to take Aciclovir 400 mg Tablets, 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.

Serious side effects:

If any of the following happen, stop taking Aciclovir 400 mg Tablets and tell your doctor immediately or go to the casualty department at your nearest hospital.

Allergic reactions (may affect up to 1 in 1,000 people)

If you have an allergic reaction, **stop taking Aciclovir 400 mg Tablets and see a doctor straight away.** The signs may include:

- rash, itching or hives on your skin
- swelling of your face, lips, tongue or other parts of your body
- shortness of breath, wheezing or trouble breathing
- collapse

Other side effects include:

Common (may affect up to 1 in 10 people)

- headache
- feeling dizzy
- feeling or being sick
- diarrhoea
- stomach pains
- rash
- skin reaction after exposure to light (photosensitivity)
- itching

- feeling tired
- unexplained fever (high temperature) and feeling faint, especially when standing up.

Uncommon (may affect up to 1 in 100 people)

- itchy, hive-like rash
- hair loss.

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

- effects on some blood and urine tests
- increases in the enzymes that work in the liver.

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

- reduced numbers of red blood cells (anaemia)
- reduced numbers of white blood cells (leukopenia)
- reduced numbers of blood platelets (cells that help blood to clot) (thrombocytopenia)
- feeling weak
- feeling agitated or confused
- shaking or tremors
- hallucinations (seeing or hearing things that aren't there)
- fits
- feeling unusually sleepy or drowsy
- unsteadiness when walking and lack of coordination
- difficulty speaking
- inability to think or judge clearly
- unconsciousness (coma)
- paralysis of part or all of your body
- disturbances of behaviour, speech and eye movements
- stiff neck and sensitivity to light
- inflammation of the liver (hepatitis)
- yellowing of your skin and whites of your eyes (jaundice)
- kidney problems where you pass little or no urine
- pain in your lower back, the kidney area of your back or just above your hip (renal pain).

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 national reporting system listed in Appendix V***. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aciclovir 400 mg 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.

6. Contents of the pack and other information

Aciclovir Tablets are available in three different strengths:
However, this leaflet applies only to 400 mg strength.

What Aciclovir 400 mg Tablets contain

The active substance is Aciclovir. Each tablet contains 400 mg of Aciclovir.

The other ingredients are:

Magnesium stearate, microcrystalline cellulose, sodium starch glycollate, pregelatinised starch and colloidal anhydrous silica.

What Aciclovir 400 mg Tablets look like and contents of the pack

Aciclovir 400 mg tablets are capsule shaped biconvex uncoated white to off-white tablets with “400” debossed on one side and “ACV” on the other side.

Aciclovir Tablets are available in packs of 56, 60, 70 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

<[To be completed nationally]>

Manufacturer:

Terapia S.A.
124 Fabricii Street
400632 Cluj-Napoca
Cluj Romania

Sun Pharmaceutical Industries Europe BV
Polarisavenue 87
2132 JH Hoofddorp
The Netherlands

This leaflet was last revised in 2018-07-04.