

Aciclovir 400mg and 800mg 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 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. See section 4.

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1 What Aciclovir is and what it is used for

Aciclovir is an antiviral medicine, which acts on infected cells by stopping the virus growing.

Aciclovir 400mg tablets are used to:

- treat or prevent herpes simplex infections of the skin and mucous membranes e.g. cold sores and genital herpes (except in children whose immune system works less well and they are unable to fight infections)
- prevent herpes simplex infections in patients whose immune system is not working properly
- treat chicken pox (varicella infection).

Aciclovir 800mg Tablets are used to:

- treat chicken pox (varicella infection)
- treat shingles (herpes zoster infection).

2 What you need to know before you take Aciclovir Tablets

Do not take Aciclovir Tablets

• if you are **allergic** to aciclovir, valaciclovir or any of the other ingredients of this medicine (listed in section 6). Do not take Aciclovir Tablets if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Aciclovir Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Aciclovir Tablets:

- if you have **kidney problems**
- if you are over 65 years of age
- if you have **nervous system abnormalities**, please tell your doctor before you start treatment with Aciclovir Tablets
- to avoid dehydration, it is important to **drink plenty of water** whilst taking Aciclovir Tablets, especially if you are elderly or taking doses of 4g a day or higher.

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

Other medicines and Aciclovir Tablets

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.

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

- **cimetidine** (used to treat peptic ulcers) **and probenecid** (used to treat gout).
- **mycophenolate mofetil** (used to stop your body rejecting transplanted organs).
- **theophylline** (used in asthma and other breathing problems).

Pregnancy, breast-feeding and fertility

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.

This medicine contains less than 1 mmol sodium (23mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3 How to take Aciclovir 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.

It is important to start treatment as soon as possible.

Swallow the tablets **with water, with or without food**.

If you experience difficulty in swallowing the 400mg or 800mg tablets they may be dispersed in a glass of water (at least 50ml) which should be stirred before drinking.

Usual doses:

- **Herpes simplex infection** (e.g. cold sores, genital herpes)

Adults

- treatment - 200mg 5 times a day at 4 hourly intervals for 5 days
- prevention - 200mg 4 times a day at 6 hourly intervals for 6-12 months
- prevention in patients whose immune system is not working properly - 200mg 4 times a day at 6 hourly intervals for the period that the patient is at risk
- patients with severely impaired kidney function - 200mg twice a day at 12 hourly intervals

If your immune system is severely impaired or you have impaired absorption from the gut, the dose may be increased or you may be given an injection (into a vein).

- **Herpes simplex infection** (e.g. cold sores, genital herpes)

Children

- treatment -
 - 2 years and over - adult dose
 - under 2 years - half the adult dose

- prevention in patients whose immune system is not working properly -
- 2 years and over - adult dose
- under 2 years - half the adult dose
- Herpes zoster infection** (shingles)
 - Adults**
 - treatment - 800mg 5 times a day at 4 hourly intervals for 7 days
 - treatment in patients with moderately impaired kidney function - 800mg 3 times a day at 6-8 hourly interval
 - treatment in patients with severely impaired kidney function - 800mg twice a day at 12 hourly intervals

- Varicella infection** (chicken pox)

Children

- treatment – for 5 days
- 6 years and over - 800mg 4 times a day
- 2-5 years - 400mg 4 times a day
- under 2 years - 200mg 4 times a day

A liquid formulation might be more suitable for small children.

Elderly

Dosage may be reduced in the elderly, especially in those whose kidneys are not working properly.

To avoid dehydration, it is important to **drink plenty of water** whilst taking Aciclovir Tablets, especially if you are elderly or taking high doses.

If you take more Aciclovir Tablets than you should

If you take too many Aciclovir Tablets, contact your doctor immediately. Signs of an overdose include effects on the stomach and intestines such as feeling or being sick and effects on the nervous system such as confusion.

If you forget to take Aciclovir Tablets

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

4 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:

- Allergic reactions** (may affect up to 1 in 1,000 people)
If you have an allergic reaction, **stop taking Aciclovir 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.

If you experience any of the following serious side effects, **stop taking Aciclovir Tablets and see a doctor straight away**.

- Very rare** (may affect up to 1 in 10,000 people)
- yellowing of your skin and whites of your eyes (jaundice).

Other side effects include:

- Common** (may affect up to 1 in 10 people)
- headache
 - feeling dizzy
 - feeling or being sick
 - diarrhoea
 - stomach pains
 - 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)
- 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)
 - 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Aciclovir Tablets

Keep this medicine out of the sight and reach of children.

Store below 25°C in a dry place.

Do not use this medicine after the expiry date, which is stated on the label, carton or bottle. 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

What Aciclovir Tablets contain

- The active substance (the ingredient that makes the tablets work) is aciclovir PhEur. Each tablet contains either 400mg or 800mg of the active substance.
- The other ingredients are:
400mg tablets: colloidal anhydrous silica, magnesium stearate, polyvidone, sodium starch glycolate, E172, E460
800mg tablets: colloidal anhydrous silica, magnesium stearate, polyvidone, sodium starch glycolate, E460.

What Aciclovir Tablets look like and contents of the pack

400mg Aciclovir Tablets are pink, circular, flat bevelled-edge, uncoated tablets. Pack size is 56.
800mg Aciclovir Tablets are white, oval, biconvex, uncoated tablets. Pack size is 35.

Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK.

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