

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 work 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, any of the ingredients of this medicine (listed in section 6) or valaciclovir .

Warnings and precautions

Talk to your doctor or pharmacist before taking Aciclovir tablets:

- 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 have **kidney problems**.

Other medicines and Aciclovir tablets

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

- **cimetidine** (used to treat peptic ulcers) **and probenecid** (used to treat gout), as these increase the concentration of aciclovir.
- **mycophenolate mofetil** (medicine used in transplant patients). Care should be taken if you are taking high doses of Aciclovir, as blood levels of both drugs may increase.
- **ciclosporin** (an immunosuppressant drug). Your doctor may monitor your kidney function.
- **theophylline** (used in asthma and other breathing problems).
- **zidovudine** (used in HIV infection).

Pregnancy and breast-feeding

There is limited information on the use of Aciclovir tablets in pregnancy or 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 drowsiness and sleepiness 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 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

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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 intervals
- 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 doses of 4g a day or higher.

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.

Contact your doctor at once if you have a **severe allergic reaction** (anaphylaxis) such as swelling of the face, lips, tongue or throat (angioedema), difficulty breathing or swallowing.

Tell your doctor or pharmacist if you notice any of the following effects or any not listed.

Common (may affect more than 1 in 10 people): dizziness, headache, feeling or being sick, diarrhoea, stomach pain, skin rashes, itching, tiredness, sensitivity to sunlight or artificial light (e.g. sunbeds), fever.

Uncommon (may affect up to 1 in 100 people): pale or red irregular raised patches with severe itching (hives), hair loss.

Rare (may affect up to 1 in 1,000 people): an increase in bilirubin and liver related enzymes, an increase in the blood levels of urea and creatinine, impaired kidney function which may progress to kidney failure (usually during treatment by injection into a vein), circular, irregular red patches on the skin of the hands and arms (erythema multiforme), severe form of skin rash with flushing, fever, blisters or ulcers (Stevens Johnson syndrome), severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis).

Very rare (may affect up to 1 in 10,000 people): inflammation of the liver (hepatitis), yellowing of the skin or whites of the eyes (jaundice), changes in the numbers and types of your blood cells (anaemia, leucopenia, thrombocytopenia). If you notice increased bruising, nosebleeds, sore throats, infections, excessive tiredness, breathlessness on exertion or abnormal paleness of the skin, you should tell your doctor who may want you to have a blood test, kidney pain (felt in the back), kidney failure, nervous system reactions including drowsiness, confusion, seeing, hearing or feeling things that are not there (hallucinations), psychotic symptoms, disease of the brain, sleepiness, convulsions (fits), coma and a feeling of general discomfort and illness, agitation, involuntary shaking, difficulty controlling movements, difficulty speaking.

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. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Aciclovir tablets

Keep 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 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 glycollate, E172, E460

800mg tablets: colloidal anhydrous silica, magnesium stearate, polyvidone, sodium starch glycollate, 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

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