

Patient Information Leaflet
ACICLOVIR 200mg, 400mg, 800mg TABLETS

Read all of this leaflet carefully before you start taking this medicine.

- 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 only for you. Do not pass it to others. It may harm them, even if their symptoms are the same as yours.
- If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT ARE ACICLOVIR TABLETS AND WHAT THEY ARE USED FOR

The name of your medicine is Aciclovir 200mg, 400mg, 800mg Tablets (called aciclovir in this leaflet). Each tablet contains either 200mg, 400mg or 800mg of the active ingredient, aciclovir. Aciclovir belongs to a group of medicines called anti-virals.

Aciclovir can be used:

- To treat herpes and other viral infections caused by the herpes virus (varicella zoster) such as chicken pox and shingles
- To prevent recurrent attacks of herpes simplex
- To help prevent those who have low immune systems from getting herpes infections.

2. BEFORE YOU TAKE ACICLOVIR TABLETS

DO NOT take Aciclovir and tell your doctor if:

- You are allergic (hypersensitive) to aciclovir, valaciclovir or any other ingredients in these tablets (see section 6: further information). An allergic reaction can include a rash, itching, shortness of breath. Do not take this medicine if any of the above apply to you, talk to your doctor or pharmacist before taking aciclovir.

Take special care with Aciclovir

Before you take aciclovir, tell your doctor if:

- You have kidney or liver disease
- You are thirsty. You must be sure you drink plenty of “liquids such as water” whilst taking this medicine
- You are an elderly patient.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using aciclovir.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines brought without a prescription, including herbal medicines.

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

- Probenecid – used for gout
- Cimetidine – used for stomach acid
- Mycophenolate mofetil – used after transplant operations.

Tests

Tell your doctor you are taking this medicine if you are going to have any blood or urine tests.

Pregnancy and breast feeding

Talk to your doctor before taking this medicine if you are pregnant, planning to become pregnant or are breast feeding.

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.

400mg, 800mg TABLETS

Take this medicine as your doctor or pharmacist has told you. Look on the label and ask the doctor or pharmacist if you are not sure.

3. How to take Aciclovir Tablets**Taking this medicine**

- Each Tablet contains either 200mg, 400mg or 800mg Aciclovir
- Take these tablets by mouth
- Drink plenty of liquids such as water while taking this medicine
- If you feel the effect of your medicine is too strong or too weak, do not change the dose yourself, but talk to your doctor or pharmacist.

The usual doses are given below. These may be changed by your doctor:

Adults:

Usually you will be given 200mg tablets, but your doctor may give you a higher dose such as 400mg or 800mg tablets. It depends on whether your doctor has prescribed the tablets for the treatment or prevention of a herpes infection, whether your immune system is intact or not and the type of disease.

Herpes Simplex

- Take for at least 5 days
- One 200mg tablet five times each day
- Take every four hours while awake (for example, 6am, 10am, 2pm, 6pm and 10pm).

Shingles and chicken pox

- Take for 7 days
- Four 200mg tablets (800mg) five times each day
- Take every four hours while awake (for example, 6am, 10am, 2pm, 6pm and 10pm).

Black

Children**Herpes simplex**

- Take for at least 5 days.

Children over 2 years

- One 200mg tablet five times each day
- Take every four hours while awake (for example, 6am, 10am, 2pm, 6pm and 10pm).

Children under 2 years

- One half of a 200mg tablet five times each day
- Take every four hours while awake.

Shingles

This medicine should not be used to treat shingles in children.

Chicken Pox

- Take for 5 days.

Age 6 years and above

- Four 200mg tablets, four times each day.

Age 2 to 5 years

- Two 200mg tablets, four times each day.

Under 2 years

- One tablet four times each day.

Elderly and people with kidney problems

Your doctor may decide to lower your dose if you are elderly or have kidney problems.

Stopping your medicine

Even if you feel well and your symptoms and lesions have gone, you should continue taking your tablets for as long as your doctor has told you. This is usually between 5 and 7 days for the treatment of acute infections and up to months for the prevention of recurrences.

If you take more aciclovir than you should

Talk to your doctor or go to your nearest hospital straight away.

If you forget to take Aciclovir 200mg, 400mg, 800mg Tablets

Do not take a double dose (two doses at the same time) to make up for a forgotten dose. Take your next dose as soon as you remember, then go on as before. However, if it is nearly time for the next dose, skip the missed dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Aciclovir Tablets can cause side effects although not everybody gets them.

If you have an allergic reaction to aciclovir see a doctor straight away.

An allergic reaction may include:

- Any kind of skin rash, flaking skin, boils or sore lips and mouth
- Swelling of the face, lips, tongue or throat and difficulty breathing or swallowing
- Sudden wheezing, fluttering or tightness of the chest or collapse.

Other side effects include:**Common (affects less than 1 in 10 people):**

- Headache, dizziness
- Feeling sick, vomiting, diarrhoea, abdominal pains
- Rashes (including rash caused due to sensitivity to sunlight)
- Fever
- Tiredness
- Itching.

Uncommon (affects less than 1 in 100 people):

- Hair loss.

Rare (affects less than 1 in 1,000 people):

- Hypersensitivity reactions
- Difficulty in breathing
- Abnormal liver function tests
- Abnormal kidney function tests
- Skin rash causing red patches and itching
- Swelling of the tissues.

Very rare (affects less than 1 in 10,000 people):

- Changes to the blood cells causing anaemia (pale skin), reduced immunity to infections, clotting disorders which may make you bruise easily
- Agitation, confusion, tremor
- Convulsions
- Coma
- Seeing or hearing things that are not present
- Yellow discoloration of the skin & eyes
- Enlarged liver
- Kidney failure
- Radiating pain in the back due to kidney problems
- Lack of coordination of muscle movements
- Sleepiness, speech disorder
- Swelling of the brain (brain disorder).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ACICLOVIR TABLETS

- Keep out of the reach and sight of children
 - Do not store above 25°C
 - Do not use after the expiry date (month, year) stated on the label and carton
 - If the medicine is out of date or you no longer need it, take the remaining tablets back to the pharmacy
 - Medicines should not be disposed of via wastewater or household waste.
- Ask your pharmacist how to dispose of medicine no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What Aciclovir Tablets contain:

- The active ingredient is aciclovir
- The other ingredients are cellulose microcrystalline, sodium starch glycolate, polyvidone K25, magnesium stearate, colloidal anhydrous silica, purified water.

What Aciclovir Tablets look like and contents of the pack:

Aciclovir 200mg Tablets are white, odourless, round, unscored tablets. Aciclovir 200mg Tablets aluminium/PVC strip blister pack contains 25 or 60 tablets.

Aciclovir 400mg Tablets are white, odourless, oblong, unscored tablets. Aciclovir 400mg Tablets aluminium/PVC strip blister pack contains 25, 56 or 60 tablets.

Aciclovir 800mg Tablets are white, odourless, oblong, scored tablets. Aciclovir 800mg Tablets aluminium/PVC strip blister pack contains 35 tablets.

Marketing Authorisation Holder and Manufacturer:

Mercury Pharmaceuticals Ltd

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