

## PATIENT INFORMATION LEAFLET

### Aciclovir 200mg, 400mg and 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 your pharmacist.
- This medicine has been prescribed only for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### In this leaflet

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

The name of your medicine is Aciclovir Tablets. This belongs to a group of medicines called antivirals.

Aciclovir Tablets can be used:

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

Aciclovir Tablets should not be used to treat herpes simplex virus (HSV) infections in newborns and babies up to 3 months old or severe HSV infections in children with low resistance to disease.

### 2. BEFORE YOU TAKE ACICLOVIR TABLETS

Do not take Aciclovir Tablets and tell your doctor if:

- you are allergic (hypersensitive) to aciclovir, valaciclovir or any other ingredients in this medicine (see section 6: Further Information). An allergic reaction can include a rash, itching or 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 Tablets.

#### Take special care with Aciclovir Tablets

Before you take Aciclovir Tablets tell your doctor if:

- you are elderly
- you have kidney problems
- you are thirsty. You must make sure you drink plenty of liquids such as water whilst taking this medicine
- you have a nervous disorder
- you have liver disease or abnormal levels of electrolytes (salts) in your blood
- you have severe breathing difficulties.

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

#### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines bought 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 in transplant patients
- theophylline - used for asthma
- zidovudine - used to treat HIV.

#### 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

You should not drive or operate machinery until you are sure that the tablets are not affecting your ability to do so.

#### Aciclovir Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### 3. HOW TO TAKE ACICLOVIR 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.

#### Taking this medicine

- To remove a tablet, press on the tablet from the blister (or bubble) side, pushing it through the foil. Do not remove the tablet from the blister until you are ready to take it
- Unless told otherwise, swallow your tablets whole with plenty of water
- Drink plenty of liquids such as water while taking this medicine
- If you feel that 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

##### Herpes Simplex

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

##### Shingles

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

#### Stopping these problems returning after you have had them

- 200mg four times each day or 400mg twice daily.

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

- 200mg four times a day

#### Children

##### Herpes Simplex

- Take for at least 5 days

##### Children over 2 years

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

##### Children under 2 years

- 100mg, five times each day
- Take every four hours while awake

#### Stopping these problems returning after you have had them

##### Children over 2 years

- 200mg four times each day or 400mg twice daily.

##### Children under 2 years

- 200mg twice daily

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

##### Children over 2 years

- 200mg four times a day

##### Children under 2 years

- 100mg four times a day

#### Shingles

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

#### Elderly and people with kidney problems

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

#### If you take more Aciclovir Tablets than you should

Talk to your doctor or go to your nearest hospital straight away. Take this leaflet and any tablets you have left to show the doctor or pharmacist.

### If you forget to take Aciclovir 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.

**Allergic reactions** (affects less than 1 in 1,000 people)

**If you have an allergic reaction to Aciclovir Tablets 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 or 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)

- feeling or being sick
- diarrhoea
- stomach pains
- headaches
- feeling dizzy
- feeling very tired
- itching
- skin rash that happens in people who are oversensitive to sunlight
- fever

Uncommon (affects less than 1 in 100 people)

- skin rashes (causing itchiness or redness)
- hair loss

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

- shortness of breath
- changes in blood tests that check the way your liver or kidneys are working

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

- blood disorders such as nose bleeds, bruising more easily than usual, sore throat, high temperatures or chills, mouth ulcers and unusual tiredness
- changes in the results of blood tests such as a fall in the number of white blood cells
- liver problems (hepatitis)
- yellowing of your skin or whites of the eyes (jaundice)
- kidney failure (which usually returns to normal)
- pain in your lower back, the kidney area of your back or above your hip (renal pain)
- feeling weak, dizzy or short of breath. This could be caused by something called 'anaemia'
- feeling agitated
- shaking
- seeing or hearing things that are not there (hallucinations)
- fits
- loss of consciousness
- feeling sleepy
- feeling confused
- difficulty in controlling movements
- difficulty in speaking
- personality changes and inability to concentrate

Frequency not known:

- tingling or numbness in the hands or feet
- muscle pain
- swollen glands
- serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome)
- serious illness with blistering of the skin (toxic epidermal necrolysis)
- swelling of the ankles, feet or fingers
- changes in vision

### 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 national reporting systems listed below.

#### United Kingdom

Yellow Card Scheme

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

#### Malta

ADR Reporting

[www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

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
- Do not store above 25°C
- Do not use after the expiry date (month, year) stated on the label and carton
- If it is out of date or you no longer want it, take it back to the pharmacy
- Do not use Aciclovir Tablets if you notice anything wrong with the medicine. Talk to your pharmacist
- 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 to protect the environment.

## 6. FURTHER INFORMATION

### What Aciclovir Tablets contain

- The tablets come in three strengths, 200mg, 400mg and 800mg.
- The active ingredient is aciclovir
- The other ingredients are gelatin, lactose, maize starch, microcrystalline cellulose, sodium starch glycollate and magnesium stearate.

### What Aciclovir Tablets look like and contents of the pack

Aciclovir 200mg Tablets are white, circular tablets marked ACV 200 on one face and CP on the reverse.

Aciclovir 400mg Tablets are white, oval tablets marked with ACV 400 and a breakline on one face and CP on the reverse.

Aciclovir 800mg Tablets are white, oval tablets marked with ACV 800 and a breakline on one face and CP on the reverse.

Aciclovir 200mg Tablets are available in blister packs of 25 and 100 tablets.

Aciclovir 400mg Tablets are available in blister packs of 25, 30, 56, 60, 70 and 100 tablets.

Aciclovir 800mg Tablets are available in blister packs of 35 tablets.

Not all pack sizes may be marketed.

### Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	Reference number
Aciclovir 200mg Tablets	PL 29831/0002
Aciclovir 400mg Tablets	PL 29831/0001
Aciclovir 800mg Tablets	PL 29831/0003

This is a service provided by the Royal National Institute of Blind People.

### Marketing Authorisation Holder and Manufacturer

**Marketing Authorisation Holder** : Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

**Manufacturer** : CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

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