

Package leaflet: Information for the user

Aciclovir 400mg/5ml Oral Suspension

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.

The name of your medicine is Aciclovir 400mg/5ml Oral Suspension but it will be referred to as Aciclovir throughout this leaflet.

What is in this leaflet

- 1. What Aciclovir is and what it is used for**
- 2. What you need to know before you take Aciclovir**
- 3. How to take Aciclovir**
- 4. Possible side effects**
- 5. How to store Aciclovir**
- 6. Contents of the pack and other information**

1. What Aciclovir is and what it is used for

Aciclovir suspension contains the active substance 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 systems work less well, which means their bodies are less able to fight infections.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Aciclovir

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Aciclovir if:

- ▶ You have kidney problems.
- ▶ You are over 65 years of age.

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

It is important that you drink plenty of water while taking Aciclovir.

Other medicines and Aciclovir

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, 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.

Aciclovir contains

Sorbitol (E420): This medicine contains 1575mg sorbitol in each 5ml which is equivalent to 315mg/ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Methyl parahydroxybenzoate (E218): May cause an allergic reaction (possibly delayed).

Propylene glycol (E1520): This medicine contains 5mg propylene glycol in each 5 ml which is equivalent to 1mg/ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

3. How to take Aciclovir

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The dose that you should take will depend on what you have been given Aciclovir for. Your doctor will discuss this with you.

Treatment of chickenpox and shingles

- ▶ The usual dose is two 5 ml spoonfuls 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 for seven days.

Treatment of cold sores and genital herpes

- ▶ The usual dose is one 2.5 ml spoonful 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 for five days, or longer if your doctor tells you to.

Suppressing cold sores and genital herpes returning after you have had them

- ▶ The usual dose is one 2.5 ml spoonful four times a day.
- ▶ You should try to space each dose by 6 hours.
- ▶ You should take Aciclovir until your doctor tells you to stop.

Suppressing cold sores and genital herpes in people whose immune systems work less well and whose bodies are less able to fight infections

- ▶ The usual dose is one 2.5 ml spoonful four times a day.
- ▶ You should try to space each dose by 6 hours.
- ▶ You should take Aciclovir until your doctor tells you to stop.

Your doctor may adjust the dose of Aciclovir if:

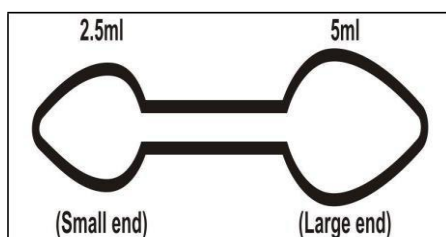
- ▶ It is for a child.
- ▶ You are over 65 years of age.
- ▶ You have kidney problems. If you have kidney problems, it is important to drink plenty of water while you are being treated with Aciclovir.

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

Method of administration

- ▶ Take this medicine by mouth.
- ▶ Use the spoon provided to carefully measure the dose needed (see figure below).
- ▶ Start to take Aciclovir as soon as possible.
- ▶ Shake the bottle well before use.
- ▶ Swallow the suspension.
- ▶ Wash the spoon with clean water after taking every dose.

2.5-5ml double-ended spoon



If you take more Aciclovir than you should

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

If you forget to take Aciclovir

- ▶ If you forget to take Aciclovir, 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.

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

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 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 are not 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 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 HPRA Pharmacovigilance Website: www.hpra.ie.

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

5. How to store Aciclovir

- ▶ 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 carton and bottle label after 'EXP'. The expiry date refers to the last day of that month.
- ▶ Do not store above 25°C.
- ▶ Do not refrigerate or freeze.
- ▶ Discard 30 days after first opening.
- ▶ Do not use this medicine if you notice that the suspension becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- ▶ 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 contains

The active substance is aciclovir.

Each 5ml of oral suspension contains 400mg aciclovir.

The other ingredients are xanthan gum (E415), sorbitol liquid (non-crystallising) (E420), methyl parahydroxybenzoate (E218), orange flavour (containing propylene glycol (E1520)), vanilla flavour (containing propylene glycol (E1520)) and purified water.

What Aciclovir looks like and contents of the pack

A white to off-white uniform oral suspension with orange and vanilla odour. It comes in an amber glass bottle with a child-resistant plastic cap. The pack also contains a 2.5-5ml double ended measuring spoon.

This medicine is available in a bottle containing 100ml of oral suspension.

POM

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This leaflet was last revised in 04/2021.