

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 stopping the growth of viruses.

Aciclovir can be used to:

- ▶ Treat chickenpox.
- ▶ Treat shingles, and when started right after the rash appears, it can help reduce the nerve pain that can exist after the shingles rash has cleared.
- ▶ Treat cold sores, genital herpes and other herpes simplex infections (but not to be used to treat herpes simplex infections in new born infants or severe herpes simplex infections in children whose immune system work less well which means their bodies are less able to fight infections).
- ▶ Stop cold sores and genital herpes returning after you have had them.
- ▶ Prevent cold sores and genital herpes in people whose immune systems work less well.

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
- ▶ You are thirsty. You must make sure you drink plenty of liquids such as water whilst taking this medicine.
- ▶ Your immune system is weak.

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

Children

There is no data available to support the use of this medicine in stopping cold sores and genital herpes returning after having had them and treatment of shingles in children whose immune systems work well.

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.

Taking Aciclovir with food and drink

Food and drink should not affect the absorption of your medicine.

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.

The ingredients in Aciclovir can pass into breast milk. If you are breast-feeding, you must check with your doctor before you take Aciclovir.

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.

Adults

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.

Stopping these problems 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.

Preventing these problems in people whose immune systems work less well

- ▶ The usual dose is one 2.5 ml spoonful four times a day. Your doctor may decide to double the dose to two 5ml spoonfuls four times daily in people whose immune system are severely impaired.
- ▶ You should try to space each dose by 6 hours.
- ▶ You should take Aciclovir until your doctor tells you to stop.
- ▶ Your doctor may decide to increase the dose or give a different form of this medicine by intravenous infusion.

Children

Your doctor may adjust the dose of Aciclovir if it is for a child.

There is no data available to support the use of this medicine in stopping cold sores and genital herpes returning after having had them and treatment of shingles in children whose immune systems work well.

Treatment of cold sores and genital herpes:

- ▶ 2 years and over: one 2.5 ml spoonful five times a day.
- ▶ Under 2 years: other forms of this medicine are more suitable for children under 2 years.

Preventing these problems in children whose immune systems work less:

- ▶ 2 years and over: one 2.5 ml spoonful four times a day.

- ▶ Under 2 years: other forms of this medicine are more suitable for children under 2 years.

Treatment of chicken pox

- ▶ 6 years and over: two 5 ml spoonfuls four times a day.
- ▶ 2-5 years: one 5 ml spoonfuls four times a day.
- ▶ Under 2 years: one 2.5 ml spoonful four times a day.
- ▶ You should try to space each dose by 5 hours.
Suggested times are: **7am, 12noon, 5pm and 10pm.**
- ▶ Your child should take Aciclovir for five days.

Your doctor may adjust the dose of Aciclovir if:

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

People over 65 years of age or with kidney problems:

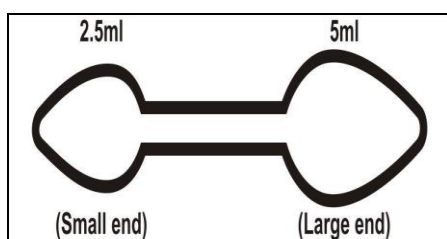
It is very important while you are taking Aciclovir that you drink water regularly during the day. This will help to reduce side effects that can affect the kidney or nervous system. Your doctor will closely monitor you for signs of these. Nervous system side effects might include feeling confused or agitated, or feeling unusually sleepy or drowsy.

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:

- ▶ Bumpy rash, itching or hives on your skin
- ▶ Swelling of your face, lips, tongue or other parts of your body (angioedema)
- ▶ Shortness of breath, wheezing or trouble breathing
- ▶ Unexplained fever (high temperature) and feeling faint, especially when standing up.

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 (fatigue)
- ▶ Fever.

Uncommon (may affect up to 1 in 100 people)

- ▶ Bumpy, itchy, hive-like rash (urticaria)
- ▶ Hair loss.

Rare (may affect up to 1 in 1,000 people)

- ▶ Difficulty breathing
- ▶ Effects on some blood and urine tests including changes in the levels of liver enzymes and blood count changes
- ▶ Swelling of you face, lips, mouth, tongue or throat (angioedema).

Very rare (may affect up to 1 in 10,000 people)

- ▶ Nosebleeds and bruising more easily than usual as a result of reduced numbers of blood platelets (thrombocytopenia)
- ▶ Reduction in the numbers of red blood cells (anaemia) and white blood cells (leukopenia)
- ▶ Feeling agitated or confused
- ▶ Shaking or tremors
- ▶ Hallucinations (Seeing or hearing things that are not there)
- ▶ Fits (seizures)
- ▶ Feeling unusually sleepy or drowsy
- ▶ Unsteadiness when walking and lack of coordination (ataxia)
- ▶ Difficulty speaking or hoarseness (dysarthria)
- ▶ Inability to think or judge clearly or concentrate
- ▶ Unconsciousness (coma)
- ▶ Disturbances of behaviour, speech and eye movements
- ▶ Damage or malfunction of the brain (encephalopathy) which is evident by an altered mental state

- ▶ 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)
- ▶ Fatigue, decreased energy, weakness, shortness of breath, light-headedness, palpitations, looking pale (anaemia).

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.

Marketing Authorisation Holder:

Syri Pharma Limited t/a Thame Laboratories
 Floor 0, 1 WML,
 1 Windmill Lane,
 Dublin 2, D02 F206, Ireland.

Manufacturer:

Syri Limited t/a Thame Laboratories,
Unit 4, Bradfield Road,
Ruislip, Middlesex,
HA4 0NU, UK.

OR

Syri Limited t/a SyriMed,
Unit 4, Bradfield Road,
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HA4 0NU, UK.

OR

Pharmadox Healthcare Ltd.,
KW20A Kordin Industrial Park,
Paola PLA3000, Malta.

If this leaflet is hard to see or read, please call +353 1437 8830 for help.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

IE and UK (NI): Aciclovir 400mg/5ml Oral Suspension

This leaflet was last revised in 08/2022.