

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

- shortness of breath
- this medicine may also cause changes in the results of blood tests such as a fall in the number of white blood cells
- changes in blood tests that check the way your liver or kidneys are working
- swelling of the face, lips, tongue or throat

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.
- feeling weak. This could be caused by something called ‘anaemia’
- feeling agitated
- shaking
- seeing or hearing things that are not there (hallucinations)
- fits
- feeling sleepy
- difficulty in controlling your movements or speech
- feeling confused
- loss of consciousness
- 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)

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 the 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 Oral Suspension

- Keep out of the reach and sight of children.
- Do not store above 25°C.
- Take back to the pharmacy 1 month after you first open it.
- 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- If it is out of date or you no longer want it, take it back to the pharmacy.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 Oral Suspension 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. Contents of the pack and other information

What Aciclovir Oral Suspension contains

- The active ingredient is aciclovir
- The other ingredients are sodium methyl hydroxybenzoate (E219), sodium propyl hydroxybenzoate (E217), citric acid (E330), xanthan gum (E415), liquid maltitol (E965), nectar flavour (contains propylene glycol (E1520)) and purified water.

What Aciclovir Oral Suspension looks like and contents of the pack

An opaque white to light beige/pink suspension with an odour of nectar. It comes in a brown glass bottle holding 100ml of suspension.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

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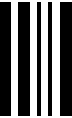


Patient Information Leaflet

Aciclovir 400mg/5ml Oral Suspension



- 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

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

1. What is Aciclovir Oral Suspension and what is it used for

The name of your medicine is Aciclovir 400mg/5ml Oral Suspension (called aciclovir in this leaflet). This 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 chickenpox and shingles
- to prevent recurrent attacks of herpes simplex
- to help prevent those who have low immune systems from getting herpes infections.

2. What do you need to know before you take Aciclovir Oral Suspension

Do not take Aciclovir and tell your doctor if:

- you are allergic (hypersensitive) to aciclovir, valaciclovir or any other ingredients in this liquid (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.

Warnings and precautions

Talk to your doctor or pharmacist before taking aciclovir if:

- you have kidney problems
- you are over 65 years of age. Your doctor may adjust your dose to reduce the risk of side effects
- you are thirsty. You must make sure you drink plenty of 'liquids such as water' whilst taking this medicine.

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

Other medicines and Aciclovir Oral Suspension

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 after transplant operations

Continued overleaf

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

Pregnancy, breast-feeding and fertility
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 feeling drowsy or sleepy may impair your ability to concentrate and react. Make sure you are not affected before you drive or operate machinery.

Important information about what is in Aciclovir Oral Suspension:
This medicine contains:

- methyl (E219) and propyl (E217) parahydroxybenzoates: May cause allergic reactions (possibly delayed).
- liquid maltitol (E965): If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- propylene glycol (E1520): This medicine contains 18.6 mg propylene glycol in each 5ml dose. 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.
- This medicine contains less than 1mmol sodium (23mg) per 5ml, that is to say essentially “sodium-free”.

3. How to take Aciclovir Oral Suspension

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

- This medicine contains 400mg of aciclovir in each 5ml
- Take this medicine by mouth
- Drink plenty of ‘liquids such as water’ while taking this medicine
- Always shake the bottle before use
- 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
A lower strength suspension (200mg/5ml) is available for the treatment of herpes simplex

- Take for at least 5 days
- 2.5ml of suspension (200mg), five times each day
- Take every four hours while awake (for example, 6am, 10am, 2pm, 6pm, 10pm)

Shingles and Chickenpox

- Take for 7 days
- Two 5ml spoonfuls (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

- adults: 2.5ml of suspension (200mg), four times each day.
- you should try to space each dose by 6 hours.
- you should take this medicine until your doctor tells you to stop.

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

- adults and children over 2 years: 2.5ml of suspension (200mg), four times each day.
- children under 2 years: 1.25ml of suspension (100mg), four times each day.
- you should try to space each dose by 6 hours.
- you should take this medicine until your doctor tells you to stop.

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Children

Herpes Simplex

- Take for at least 5 days

Children over 2 years

- 2.5ml of suspension (200mg), five times each day
- Take every four hours while awake (for example, 6am, 10am, 2pm, 6pm, 10pm)

Children under 2 years

- 1.25ml of suspension (100mg), five times each day
- Take every four hours while awake (for example, 6am, 10am, 2pm, 6pm, 10pm)

Chickenpox

- Take for 5 days

Age 6 and above

- Two 5ml spoonfuls (800mg), four times each day

Age 2 to 5 years

- One 5ml spoonful (400mg), four times each day

Under 2 years

- 2.5ml of suspension (200mg), 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.

If you take more aciclovir than you should
Talk to your doctor or go to your nearest hospital straight away. Take the medicine pack with you.

If you forget to take Aciclovir Oral Suspension
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 Oral Suspension 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 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

If you get any of the following side effects, stop taking aciclovir and see your doctor as soon as possible:

Common (affects less than 1 in 10 people)

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

Uncommon (affects less than 1 in 100 people)

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

Continued overleaf