



AZEVENDOS Aciclovir 250 mg PIL
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PACKAGE LEAFLET: INFORMATION FOR THE USER

Aciclovir 250 mg powder for solution for infusion

Aciclovir sodium

Read all of this leaflet carefully before you are given 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.
- 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.

What is in this leaflet:

1. What Aciclovir is and what it is used for
2. What you need to know before you are given Aciclovir
3. How to use 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 250 mg powder for solution for infusion contains a medicine called 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 recurrent chickenpox and shingles in people whose immune system works well
- treat primary and recurrent chickenpox and shingles in people whose immune systems work less well, which means their bodies are less able to fight infections
- treat severe cases of genital herpes
- treat and stop cold sores and genital herpes in people whose immune systems work less well, which means their bodies are less able to fight infections
- treat serious virus infections in children up to 3 months of age. This can rarely be caused by the virus responsible for cold sore infection and genital herpes
- treat inflammation of the brain. This can rarely be caused by the virus responsible for cold sore infection and genital herpes.

2. What you need to know before you are given Aciclovir

Do not use Aciclovir

- if you are allergic to aciclovir or valaciclovir or any of the other ingredients of this medicine (listed in Section 6).

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 immune system is weak.

If you are not sure if 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
- tacrolimus, ciclosporin or mycophenolate mofetil, used to stop your body rejecting transplanted organs
- lithium, used in the treatment of manic-depressive disorders
- theophylline, used in the treatment of certain respiratory diseases.

Pregnancy and breast-feeding

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

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 sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium-free".

3. How to use Aciclovir

You will never be expected to give yourself this medicine. It will always be given to you by a person who is trained to do so.

Before the medicine is given to you it will be diluted.

Aciclovir will be given to you as a continuous infusion into your vein. This is where the drug is slowly given to you over a period of time.

The dose you will be given, the frequency and the duration of the dose will depend on:

- the type of infection you have
- your weight
- your age.

Your doctor may adjust the dose of Aciclovir if you have kidney problems.

For people over 65 years of age or with kidney problems, it is important you receive plenty of fluids while you are being treated with Aciclovir. This will help to reduce side effects that can affect the kidneys 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 having Aciclovir if any of the above applies.

If you are given too much Aciclovir

If you think you have been given too much Aciclovir, talk to your doctor or nurse straight away.

If you have been given too much Aciclovir you may:

- feel confused or agitated
- have hallucinations (seeing or hearing things that aren't there)
- have fits
- become unconscious (coma).



The following information is intended for healthcare professionals only

For single use only.
Prepare immediately prior to use.

Reconstitution

Aciclovir should be reconstituted using the following volumes of either Water for Injections or Sodium Chloride Intravenous Injection (0.9% w/v) to provide a solution containing 25 mg Aciclovir per ml:

	Volume of fluid for reconstitution	Volume following reconstitution
250 mg vial	10 ml	10.1 – 10.2 ml

From the calculated dose, determine the appropriate number and strength of vials to be used.

To reconstitute each vial add the recommended volume of infusion fluid and shake gently until the contents of the vial have dissolved completely. The solution reconstituted with Water for Injections or sodium chloride intravenous injection (0.9% w/v) is stable for a period of 12 hours at temperature below 25°C or in a refrigerator (2°C – 8°C).

Administration

The required dose of Aciclovir should be administered by slow intravenous infusion over a one-hour period.

After reconstitution, Aciclovir may be administered by a controlled-rate infusion pump. Alternatively, the reconstituted solution may be further diluted to give an aciclovir concentration of not greater than 5 mg/ml (0.5% w/v) for administration by infusion.

Add the required volume of reconstituted solution to the chosen infusion solution, as recommended below, and shake well to ensure adequate mixing occurs.

For children and neonates, where it is advisable to keep the volume of infusion fluid to a minimum, it is recommended that dilution is on the basis of 4 ml reconstituted solution (100 mg aciclovir) added to 20 ml of infusion fluid.

For adults, it is recommended that infusion bags containing 100 ml of infusion fluid are used, even when this would give an aciclovir concentration substantially below 0.5% w/v. Thus one 100 ml infusion bag may be used for any dose between 250 and 500 mg aciclovir (10 ml of reconstituted solution) but a second bag must be used for doses between 500 mg and 1000 mg.

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 10,000 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
 - unexplained fever (high temperature) and feeling faint, especially when standing up.
- Other side effects include:

Common (may affect up to 1 in 10 people)

- feeling or being sick
- itchy, hive-like rash
- skin reaction after exposure to light (photosensitivity)
- itching
- swelling, redness and tenderness at the site of injection
- increase in liver enzymes
- increases in blood urea and creatinine (that can determine kidney function, which may be detected through a blood test).

Uncommon (may affect up to 1 in 100 people)

- reduced numbers of red blood cells (anaemia)
- reduced numbers of white blood cells (leukopenia)
- reduced numbers of blood platelets (cells that help the blood to clot) (thrombocytopenia).

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

- headache or feeling dizzy
- diarrhoea or stomach pains
- feeling tired
- fever
- effects on some blood urine tests
- feeling weak
- feeling agitated or confused
- shaking or tremors
- hallucinations (seeing or hearing things that aren't 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 just above your hip (renal pain)
- damage or malfunction of the brain (encephalopathy) which is evident by an altered mental state.

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:

UK: the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard.

Ireland: HPRA Pharmacovigilance, Earlsfort

Terrace, IRL - Dublin 2; Tel: +353 1 6764971;

Fax: +353 1 6762517. Website: www.hpra.ie;

E-mail: medsafety@hpra.ie.

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



Aciclovir when diluted in accordance with the above schedule will give an aciclovir concentration not greater than 0.5% w/v.

Since no antimicrobial preservative is included, reconstitution and dilution must be carried out under full aseptic conditions, immediately before use, and any unused solution discarded.

5. How to store Aciclovir

Keep this medicine out of the sight and reach of children.

Store in the original package.

For reconstituted solutions, chemical and physical in-use stability has been demonstrated for 12 hours at 25°C or in a refrigerator (2°C – 8°C).

From a microbiological point of view, once opened, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 12 hours at 2–8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

When diluted in accordance with the recommended schedules, Aciclovir is known to be compatible with the following infusion fluids (see table below).

Do not use this medicine after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

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 vial contains 250 mg of aciclovir (as aciclovir sodium). The other ingredient is sodium hydroxide.

What Aciclovir looks like and contents of the pack

Aciclovir is available in vials containing a white powder, sealed with a stopper made of bromobutyl rubber, a cap made of aluminium and a plastic polypropylene lid.

Aciclovir is available in packs containing 1, 5 or 10 units.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Laboratórios Azevedos –
Indústria Farmacêutica, S.A.
Estrada Nacional 117-2,
Alfragide
2614-503 Amadora,
Portugal

Manufacturer

Sofarimex –
Indústria Química e Farmacêutica, S.A.
Av. das Indústrias,
Alto do Colaride
2735-213 Cacém,
Portugal

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When diluted in accordance with the recommended schedules, Aciclovir is known to be compatible with the following infusion fluids:

	Room temperature (15°C – 25°C)	Refrigerator (2°C – 8°C)
Sodium Chloride Intravenous Infusion (0.9% w/v)	24 hours	24 hours
Sodium Chloride (0.18% w/v) and Glucose (4% w/v) Intravenous Infusion	12 hours	Do not refrigerate or freeze
Sodium Chloride (0.45% w/v) and Glucose (2.5% w/v) Intravenous Infusion	24 hours	8 hours
Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution) – after reconstituted with purified water	Do not store below 25°C	12 hours
Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution) - after reconstituted with Sodium Chloride (0.9% w/v)	Do not store below 25°C	8 hours

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