

Package leaflet: Information for the user

Aciclovir 25 mg/ml concentrate for solution for infusion (Sterile Concentrate) Aciclovir sodium

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Aciclovir Sterile Concentrate is and what it is used for
2. What you need to know before you use Aciclovir Sterile Concentrate
3. How to use Aciclovir Sterile Concentrate
4. Possible side effects
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1. What Aciclovir Sterile Concentrate is and what it is used for

Aciclovir 25 mg/ml concentrate for solution for infusion contains aciclovir. This belongs to a group of medicines called antivirals. It works by stopping the growth of viruses.

Aciclovir Sterile Concentrate can be used in patients with a working immune system to:

- treat recurring chicken-pox and shingles
- treat severe first cases of genital herpes

In patients with an impaired immune system (which means their bodies are less able to fight infections) to:

- treat primary and recurring chickenpox and shingles
- treat and stop cold sores and genital herpes
- prevent *herpes simplex* infections

It can also be used to:

- treat inflammation of the brain caused by the virus responsible for cold sore infection and genital herpes
- treat *herpes simplex* infections in very young babies or in infants up to 3 months of age

2. What you need to know before you use Aciclovir Sterile Concentrate

Do not use Aciclovir Sterile Concentrate if:

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Aciclovir Sterile Concentrate if:

- if you have kidney problems
- if you are over 65 years of age
- your immune system is weakened

If you are not sure if the above apply to you, talk to your doctor, pharmacist or nurse before using Aciclovir Sterile Concentrate.

Other medicines and Aciclovir Sterile Concentrate

Tell your doctor, pharmacist or nurse if you are using or have recently used any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

In particular tell your doctor, pharmacist or nurse if you are taking any of the following medicines:

- probenecid, used to treat gout
- cimetidine, used to treat stomach ulcers
- tacrolimus, cyclosporin or mycophenolate mofetil, used to stop your body rejecting transplanted organs
- theophylline (a medicine used to treat some breathing disorders)
- lithium (a medicine used for bipolar disorder)

Pregnancy, breast-feeding and fertility

If you are pregnant or think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

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

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 Sterile Concentrate contains sodium

This medicine contains 26.7 mg sodium (main component of cooking/table salt) in each vial of 10 ml solution. This is equivalent to 1.34% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 53.4 mg sodium (main component of cooking/table salt) in each vial of 20 ml solution. This is equivalent to 2.67% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 106.8 mg sodium (main component of cooking/table salt) in each vial of 40 ml solution. This is equivalent to 5.34% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Aciclovir Sterile Concentrate

How your medicine is given

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.

Aciclovir Sterile Concentrate 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. You may be given fluids to ensure you do not become dehydrated.

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 and body size
- your age.

Your doctor may adjust the dose of Aciclovir Sterile Concentrate if:

- you have kidney problems.

People over 65 years of age or with kidney problems:

It is very important while you are taking Aciclovir Sterile Concentrate 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.

If you are given more Aciclovir Sterile Concentrate than you should

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

If you have been given more aciclovir than you should, you may:

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

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 Sterile Concentration 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

If any of the following happen, tell your doctor immediately (may affect up to 1 in 10,000 people):

- unexplained fever and feeling faint, especially when standing up
- changes in your blood cells e.g. anaemia and/or reduced white blood cells and/or lowered platelet levels (leading to unexplained bruising). Your doctor may take blood samples to monitor for these
- a severe form of rash with itchy pink-red blotches, which may blister (erythema multiforme)
- a rare disorder of the blood clotting system called thrombotic thrombocytopenic purpura, which may give you bruising, headaches, hallucinations and also blood clots in the kidneys if you have a compromised immune system
- a severe form of anaemia called haemolytic uraemic syndrome, which may make you look pale and feel tired due to anaemia, and give you bruising and kidney problems if you have a compromised immune system

Other side effects include:

Common (may affect up to 1 in 10 people)

- inflammation along the vein used for the infusion
- feeling or being sick
- itchy, bumpy, hive-like rash
- skin reaction after exposure to light (photosensitivity)
- itching
- swelling, redness and tenderness at the site of infusion
- increases in liver related enzymes which may be detected through a blood test
- increases in blood urea and creatinine which may be detected through a blood test

Uncommon (may affect up to 1 in 100 people)

- nosebleeds and bruising more easily than usual as a result of a decrease in blood platelets
- decreased energy, weakness, shortness of breath, light-headedness, palpitations, looking pale (anaemia)
- a decrease in the number of white blood cells found in blood (leukopenia). This may leave a patient more prone to infection
- reduced numbers of blood platelets (thrombocytopenia)

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

- sweating
- headache
- feeling dizzy
- abdominal pain
- diarrhoea or stomach pains
- feeling very tired (fatigue)
- fever
- inflammation at the injection site

- feeling agitated or confused (psychosis)
- shaking or tremors
- hallucinations (seeing or hearing things that aren't 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)
- difficulty breathing
- disturbances of behaviour and speech and bodily movements
- inflammation of the liver (hepatitis)
- yellowing of your skin and whites of your eyes (jaundice)
- kidney problems or failure where you pass little or no urine (including blood in 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

Not known (frequency cannot be estimated from the available data)

- thirst
- low blood pressure (you may feel dizzy when you stand up)
- rupture of red blood cells (haemolysis)
- problems with small blood vessels (leukocytoclastic vasculitis)
- tingling or numbness

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aciclovir Sterile Concentrate

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 label and carton after "EXP". The expiry date refers to the last day of that month.

Storage

Do not store above 25°C. Do not refrigerate or freeze.

Visible signs of deterioration

Do not use this medicine if you notice visible particles in it.

6. Contents of the pack and other information

What Aciclovir Sterile Concentrate contains

- The active substance is aciclovir. Each millilitre (ml) of sterile concentrate contains 25 milligrams (mg) of aciclovir (as aciclovir sodium).
- The other ingredients are: sodium hydroxide (see section 2 “Aciclovir Sterile Concentrate contains sodium”) and Water for Injections. Sodium hydroxide and/or hydrochloric acid are used to adjust the pH of the solution.

What Aciclovir Sterile Concentrate looks like and contents of the pack

Aciclovir Sterile Concentrate is a concentrate for solution for infusion (sterile concentrate). This means it is a concentrated solution, which is diluted then given as an infusion (drip). It comes in glass containers called vials.

It may be supplied in packs containing:

- 5 x 250 mg/10 ml vials
- 5 x 500 mg/20 ml vials
- 1 x 1 g/40 ml vial

Not all pack sizes may be marketed.

Marketing authorisation holder

Hospira UK Limited, Walton Oaks, Walton-On-The-Hill, Dorking Road, Tadworth, Surrey, KT20 7NS, UK

Manufacturer

Pfizer Service Company BV, Hoge Wei 10, 1930 Zaventem, Belgium

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

Belgium: Aciclovir Hospira 25 mg/ml concentraat voor oplossing voor infusie
 Denmark: Aciclovir Pfizer
 Finland: Aciclovir Pfizer
 Ireland: Aciclovir 25 mg/ml concentrate for solution for infusion
 Luxembourg: Aciclovir Hospira 25 mg/ml solution à diluer pour perfusion
 Netherlands: Aciclovir Hospira 25 mg/ml concentraat voor oplossing voor infusie
 Portugal: Faulviral
 Sweden: Aciclovir Pfizer
 United Kingdom (Northern Ireland): Aciclovir 25 mg/ml concentrate for solution for infusion

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 The following information is intended for medical or healthcare professionals only:

Please refer to the Summary of Product Characteristics (SPC) for complete prescribing information.

Further to the information included in section 3, practical information on the preparation/handling of the medicinal product is provided here.

Incompatibilities

Aciclovir sodium is reported to be incompatible with solutions of amifostine, amsacrine, aztreonam, diltiazem hydrochloride, dobutamine hydrochloride, dopamine hydrochloride, fludarabine phosphate, foscarnet sodium, idarubicin hydrochloride, meropenem, morphine sulphate, ondansetron hydrochloride, pethidine hydrochloride, piperacillin sodium - tazobactam sodium, sargramostim and vinorelbine tartrate.

Do not use bacteriostatic water for injection containing parabens or benzyl alcohol.

Biologic or colloidal fluids (e.g. blood products, protein containing solutions) are incompatible with aciclovir sodium.

Instructions for use and handling

For intravenous infusion only

Aciclovir 25 mg/ml Concentrate for Solution for Infusion contains no preservative. Dilution should therefore be carried out immediately before use under full aseptic conditions and any unused solution should be discarded.

Refrigeration is not recommended as precipitation may occur.

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 mg and 500 mg aciclovir but a second bag must be used for doses between 500 and 1000 mg. Aciclovir 25 mg/ml Concentrate for solution for Infusion should not be diluted to a concentration greater than 5 mg/ml (0.5% w/v) for administration by infusion. After addition of Aciclovir 25 mg/ml Concentrate for solution for Infusion to an infusion solution the mixture should be shaken to ensure thorough mixing.

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 of solution (100 mg aciclovir) added to 20 ml of infusion fluid.

When diluted in accordance with the recommended schedules, Aciclovir 25 mg/ml Concentrate for Solution for Infusion is known to be compatible with the infusion fluids listed below:

- Sodium Chloride Intravenous Infusion 0.9% w/v
- Sodium Chloride (0.18% w/v) and Glucose (4% w/v) Intravenous Infusion
- Sodium Chloride (0.9% w/v) and Glucose (5% w/v) Intravenous Infusion
- Sodium Chloride (0.45% w/v) and Glucose (2.5% w/v) Intravenous Infusion
- Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution)

Aciclovir 25mg/ml Concentrate for Solution for Infusion contains no preservative.

Should any visible turbidity or crystallisation appear in the solution before or during infusion, the preparation should be discarded.