

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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6. Contents of the pack and other information

1. What Aciclovir Sterile Concentrate is and what it is used for

Aciclovir Sterile Concentrate is an anti-viral medicine. It is used:

- to treat severe genital herpes
- to prevent or treat *Herpes simplex* infections (may appear as cold sores around the lips or as blisters on any part of the skin including the genitals) in patients whose immune system is not working properly
- to treat *Varicella zoster* viral infections (chicken pox and shingles)
- to treat herpes encephalitis (inflammation of the brain following infection with herpes)
- to 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 you are allergic to aciclovir or valaciclovir or any of the other ingredients of this medicine (listed in section 6).

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

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

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

It is important that you drink plenty of water while using Aciclovir Sterile Concentrate.

Other medicines and Aciclovir Sterile Concentrate

Tell your doctor or pharmacist if you are using, have recently used or might use any other 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
- theophylline (a medicine used to treat some breathing disorders)
- lithium (a medicine used for manic-depressive disorder)

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 using this medicine.

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 use Aciclovir Sterile Concentrate

This medicine will be diluted with a solution such as sodium chloride 0.9% before it is given to you. It will be given to you by a slow infusion (drip) into a vein over a period of at least 1 hour. You may be given fluids to ensure you do not become dehydrated.

If Aciclovir Sterile Concentrate accidentally gets into your eyes or onto your skin, tell your doctor or nurse immediately so that it may be washed away.

Dosage

The dose of medicine given to you and how often you are given it will be determined by your doctor and will depend on your medical condition, age, size and how well your kidneys are working.

Treatment with aciclovir usually lasts 5 days depending on how quickly you get better. However, treatment for herpes encephalitis usually lasts for at least 10 days. For very young babies treatment for herpes typically lasts 14 days for skin/eye/mouth infections and for 21 days for infections affecting the whole body.

If aciclovir is being given to prevent a viral infection, it will be given for the period your doctor thinks you are at risk of getting an infection.

If you are given more or too little Aciclovir Sterile Concentrate

This medicine will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns.

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)

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following happen, tell your doctor immediately:

- severe allergic reaction – you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint
- 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
- yellowing of the skin and whites of the eyes (jaundice)
- pain or swelling at the injection site during or immediately after the injection
- convulsions or fits
- confusion or unusual and disordered thoughts (psychosis)
- hallucinations
- agitation
- trembling or shaking
- coma
- difficulty breathing, shortness of breath
- difficulty in controlling movements
- problems with your speech
- kidney problems or failure, including blood in urine
- a severe form of rash with itchy pink-red blotches (erythema multiforme), which may blister

- in patients who have a compromised immune system:
 - 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
 - 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

These side effects are very rare.

Other side effects

Common: may affect up to 1 in 10 people

- inflammation (soreness, redness and swelling) along the vein used for the infusion
- feeling or being sick
- rash, hives or sensitivity of the skin to light
- changes in your liver and kidney function (Your doctor may take blood samples to monitor for these)
- nausea
- vomiting

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 (thrombocytopenia)

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

- sweating or fever
- headache
- abdominal pain
- diarrhoea
- dizziness
- tiredness
- feeling unusually sleepy
- problem of the brain (encephalopathy)
- pain in your lower back, the kidney area of your back or pain when passing urine (renal pain)

Frequency unknown (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.

Visible signs of deterioration

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

6. Content 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 x1 g/40 ml vial

Not all pack sizes may be marketed.

Marketing authorisation holder

Hospira UK Limited, Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, UK

Manufacturer responsible for batch release in Europe

Hospira UK Limited, Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, UK or Pfizer Service Company BVBA, Hoge Wei 10, 1930 Zaventem, Belgium

Manufacturer

Hospira Australia Pty Ltd, 1-5 7-23 and 25-39 Lexia Place, MULGRAVE VIC 3170, Australia

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The following information is intended for healthcare professionals only:

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.