

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Aciclovir 250 mg and 500 mg

Powder for solution for infusion

aciclovir

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 nurse.
- If you get any side effects, talk to your doctor or nurse. 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 use 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 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 *Varicella Zoster* infestations (chickenpox).
- treat severe cases of genital herpes.
- prevent and treat *Herpes Simplex* infections (cold sores and genital herpes) in people whose immune systems work less well, which means their bodies are less able to fight infections.
- treat *Herpes Simplex* 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 *Herpes Encephalitis* (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 USE ACICLOVIR

Do not use Aciclovir:

- if you are allergic (hypersensitive) 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 nurse before using Aciclovir.

Check with your doctor or nurse before having Aciclovir if:

- you have kidney problems
- you are over 65 years of age.

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

Other medicines and Aciclovir

Tell your doctor if you are taking, have recently taken 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;
- lithium, used to treat manic-depressive disorders;
- theophylline, used to treat some breathing disorders.

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 for advice before using this medicine.

Aciclovir contains sodium

Aciclovir Hikma 250 mg:

This medicine contains 26.2 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 1.31% of the recommended maximum daily dietary intake of sodium for an adult.

Aciclovir Hikma 500 mg:

This medicine contains 52.2 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 2.61% of the recommended maximum daily dietary intake of sodium for an adult.

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 of 1 hour.

Aciclovir is usually given every 8 hours.

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,
- your age.

Your doctor may adjust the dose of Aciclovir if:

- you have kidney problems. If you have kidney problems, it is important you receive plenty of fluids while you are being treated with Aciclovir.
- you are overweight.
- you are elderly.

Talk to your doctor before having Aciclovir if any of the above applies.

Use in children

The dose of Aciclovir given to:

- children between 3 months and 12 years of age is calculated based on body surface area.
- newborns and infants up to 3 months of age is calculated based on body weight.

If a child has kidney problems the dose of this medicine may be reduced.

If you use more Aciclovir than you should

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).

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 (affects less than 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.



The following information is intended for healthcare professionals only:

Aciclovir 250 mg and 500 mg

Powder for solution for infusion

Aciclovir

Shelf-life on the in-use stability after reconstitution and dilution

Chemical and physical in-use stability has been demonstrated for 12 hours at 15°C - 25°C.

From a microbiological point of view, 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.

Special precautions for disposal and other handling

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:

Formulation	Volume of fluid for reconstitution
250 mg vial	10 ml
500 mg vial	20 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.

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 mg and 500 mg aciclovir (10 and 20 ml of reconstituted solution) but a second bag must be used for doses between 500 mg and 1000 mg.

When diluted in accordance with the recommended schedules, Aciclovir is known to be compatible with the following infusion fluids and stable for up to 12 hours at room temperature (15°C to 25°C):

- Sodium Chloride Intravenous Infusion (0.45% and 0.9% w/v)
- Sodium Chloride (0.18% w/v) and Glucose (4% 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 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.

The reconstituted or diluted solutions should not be refrigerated.

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

Other side effects include:**Common** (affects less than 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.

Uncommon (affects less than 1 in 100 people)

- nosebleeds and bruising more easily than usual.

Very rare (affects less than 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).

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: 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

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

Store below 25°C.

Prepare immediately before use. Unused solution should be discarded.

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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Aciclovir contains**

- The active substance is aciclovir.
 - Each vial contains 250 mg of aciclovir as the sodium salt.
 - Each vial contains 500 mg of aciclovir as the sodium salt.
- The other ingredient is sodium hydroxide.

What Aciclovir looks like and contents of the pack

Aciclovir is supplied in glass vials containing a white powder, closed with a rubber stopper and sealed with a flip-off cap.

The 250 mg strength is available in 10 ml vials, in a box containing 5 and 10 vials.

The 500 mg strength is available in 20 ml vials, in a box containing 5 and 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Hikma Farmacêutica (Portugal), S.A.
Estrada do Rio da Mó, 8, 8A e 8B – Fervença
2705-906 Terrugem SNT
Portugal

Manufacturer:

Hikma Farmacêutica (Portugal), S.A.
Estrada do Rio da Mó, 8, 8A e 8B – Fervença
2705-906 Terrugem SNT
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or

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Distributed by:

Consilient Health (UK) Ltd.
No. 1 Church Road, Richmond upon Thames, Surrey,
TW9 2QE

This medicinal product is authorised in the Member States of the EEA under the following names:

France: Aciclovir Hikma 250mg et 500 mg Poudre pour solution pour perfusion
Germany: Aciclovir Hikma 250 mg und 500 mg, Pulver zur Herstellung einer Infusionslösung
Italy: Aciclovir Hikma 250 mg e 500 mg Polvere per soluzione per infusione
Portugal: Aciclovir Hikma, 250 mg e 500 mg, Pó para solução para perfusão
Poland: Aciclovir Hikma 250 mg i 500 mg proszek do sporządzenia roztworu do infuzji
Spain: Aciclovir Hikma 250 mg Polvo para solución para perfusión
United Kingdom: Aciclovir 250mg and 500 mg Powder for solution for infusion

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