

# Hikma Acyclovir® 250 & 500 mg Vials

Acyclovir (as sodium)

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed 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 the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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**1. What Hikma Acyclovir is and what it is used for**

Hikma Acyclovir contains a medicine called acyclovir. This belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses.

Hikma Acyclovir can be used to:

- treat chickenpox
- 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. Before you take Hikma Acyclovir****Do not take Hikma Acyclovir if:**

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

Do not take Hikma Acyclovir if the above applies to you. If you are not sure, talk to your doctor or pharmacist before having Hikma Acyclovir.

**Take special care with Hikma Acyclovir**

Your doctor or healthcare provider should know 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 pharmacist before taking Hikma Acyclovir.

It is important that you drink plenty of water while taking Hikma Acyclovir.

**Taking other medicines, herbal or dietary supplements**

Please tell your doctor, healthcare provider or pharmacist if you are taking or have recently taken any other medicines, including herbal medicines or medicines obtained without a prescription. These medicines may be affected by Hikma Acyclovir, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines, especially if you are taking:

- probenecid, used to treat gout
- cimetidine, used to treat stomach ulcers
- tacrolimus, ciclosporin or mycophenolate mofetil, used to stop your body rejecting transplanted organs.

**Pregnancy and breast feeding**

Please tell your doctor, healthcare provider or pharmacist if you are pregnant or intend to become pregnant, breast-feeding or plan to breastfeed.

Please ask your doctor, healthcare provider or pharmacist for advice before taking any medicine.

**Important information about some of the ingredients of Hikma Acyclovir**

Hikma Acyclovir contains sodium. To be taken into consideration by patients on a controlled sodium diet.

**3. How to take Hikma Acyclovir**

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.

Hikma Acyclovir 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 Hikma Acyclovir if:**

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

Talk to your doctor before having Hikma Acyclovir if any of the above apply.

**If you take more Hikma Acyclovir than you should**

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

If you have been given too much Hikma Acyclovir you may:

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

If you have any further questions on the use of this product, ask your doctor, healthcare provider or pharmacist.

**4. Possible side effects**

Like all medicines, Hikma Acyclovir can cause side effects, although not everybody gets them.

**Allergic reactions** (may affect up to 1 in 10,000 people)

If you have an allergic reaction, stop taking Hikma Acyclovir 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 the liver enzymes.

**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).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, healthcare provider or pharmacist.

**5. How to store Hikma Acyclovir**

The hospital will keep Hikma Acyclovir according to the correct storage conditions.

Keep out of the reach and sight of children.

Store below 30°C. Store in the original carton.

Do not use Hikma Acyclovir after the expiry date which is stated on the label and carton after Exp. Date.

The expiry date refers to the last day of that month.

Do not use Hikma Acyclovir if you notice visible signs of deterioration.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help protect the environment.

**6. Further information****What Hikma Acyclovir contains**

The active substance is acyclovir.

The other ingredient is sodium hydroxide.

**What Hikma Acyclovir looks like and content of the pack**

Hikma Acyclovir is a white powder having characteristics appearance of products prepared by freeze drying in 20 ml clear tubular type I glass vials with grey Iyo-rubber stoppers and aluminium caps.

Pack size: 5 vials.

**Marketing Authorization Holder**

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**For any information about this medicinal product, please contact the local representative of the**

**Marketing Authorization Holder.**

This leaflet was last approved in 01/2016; version number 1.1.

**To report any side effect (s)**

• Jordan Food and Drug Administration- Rational Drug Use and Pharmacovigilance department.

Email: jpc@jda.jo

Website: www.jda.jo

**The following information is intended for healthcare professionals only:****Reconstitution:**

Hikma Acyclovir should be reconstituted using the following volumes of either Water for Injections BP or Sodium Chloride Intravenous Injection BP (0.9% w/v) to provide a solution containing 25 mg acyclovir 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 Hikma Acyclovir should be administered by slow intravenous infusion over a one-hour period.

After reconstitution Hikma Acyclovir may be administered by a controlled-rate infusion pump.

Alternatively, the reconstituted solution may be further diluted to give an acyclovir 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 acyclovir) 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 acyclovir 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 acyclovir (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, Hikma Acyclovir is known to be compatible with the following infusion fluids:

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

Hikma Acyclovir when diluted in accordance with the above schedule will give an acyclovir 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.

However, if any particular circumstances force the storage of the reconstituted/diluted solutions before use, it is recommended to be done at 15-25°C for up to 12 hours after reconstitution/dilution, since there are no available data for the behavior of the product after this storage period.

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

**Council of Arab Health Ministers, Union of Arab Pharmacists****THIS IS A MEDICAMENT**

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

