1. NAME OF THE MEDICINAL PRODUCT

Aciclovir for Infusion is a liquid medicine that contains aciclovir in a slow injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 250mg of the active ingredient, aciclovir (as the sodium salt), as a powder.

The other ingredient is sodium hydroxide.

For a full list of excipients, see section 6.1 Packaging and LABEL.

3. PHARMACEUTICAL FORM

Aciclovir for Infusion is a slow injection.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Aciclovir is contraindicated for the treatment of herpes simplex infections in immunocompromised patients (e.g. patients with AIDS) or severe immunosuppression.

Aciclovir for Infusion is indicated for the prophylaxis of herpes simplex infections in immunocompromised patients.

Aciclovir for Infusion is indicated for the treatment of herpes simplex infections in patients with impaired creatinine clearance.

Aciclovir for Infusion is contraindicated for the treatment of herpes simplex infections in neonates and infants under 3 months of age.

4.2. Posology and method of administration

Aciclovir for Infusion is a slow injection.

A course of treatment with aciclovir for Infusion usually lasts five days, but may be adjusted according to the patient’s response to therapy. For the treatment of herpes simplex virus in immunocompromised adults, a course of treatment with aciclovir for Infusion may last two to three days. The recommended dosing schedule is based on the weight of the patient and the anatomical or systemic severity of the infection.

Dose for children

Aciclovir for Infusion is contraindicated for the treatment of herpes simplex infections in neonates and infants under 3 months of age.

In neonates dosed with intravenous aciclovir based on actual body weight, higher plasma concentrations may be achieved in neonates because of differences in pharmacokinetics and physiologic differences.

Dosage and administration

Rapid increases in blood urea and creatinine levels are believed to be related to peak plasma levels and the state of hydration of the patient. To avoid this effect the drug should not be given as an intravenous bolus injection but administered by a controlled-rate infusion pump.

Aciclovir for Infusion is a slow injection.

Aciclovir can get into human breast milk. You should let your doctor know if you are breast-feeding or want to start breast-feeding.

For a full list of excipients, see section 6.1 Packaging and LABEL.

5. INTERACTIONS

5.1. General

The following information is intended for healthcare professionals only:

Aciclovir is contraindicated for the treatment of herpes simplex infections in immunocompromised patients (e.g. patients with AIDS) or severe immunosuppression.

In neonates dosed with intravenous aciclovir based on actual body weight, higher plasma concentrations may be achieved in neonates because of differences in pharmacokinetics and physiologic differences.

In pediatric patients with impaired renal function, a dosage adjustment may be necessary if the plasma level of aciclovir is to be maintained.

Aciclovir for Infusion is contraindicated for the treatment of herpes simplex infections in neonates and infants under 3 months of age.

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In pediatric patients with impaired renal function, a dosage adjustment may be necessary if the plasma level of aciclovir is to be maintained.
1. NAME OF THE MEDICINAL PRODUCT

Taking other medicines
If any of the above statements apply to you, speak to your doctor or nurse before you are given Aciclovir for Infusion.

• are dehydrated (extremely thirsty)

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

2.5 to 50 ml/min The dose recommended above (5 or 10 mg/kg bodyweight) should be given
Creatinine Clearance Dosage

dosage reduction in obese patients and especially in those with renal impairment or the elderly.

given aciclovir for infusion in doses of 10mg/kg bodyweight every eight hours provided renal function is not
infections in the neonate and infant up to

Aciclovir for infusion is indicated for the prophylaxis of Herpes simplex infections in immunocompromised patients.

Each vial contains 26mg of sodium. You should tell your doctor or pharmacist if you are on a controlled sodium diet.

• Probenecid, a drug used to prevent gout (arthritis in the joints).

4. POSSIBLE SIDE EFFECTS

If you get any side effects, talk to your doctor or pharmacist. This includes any effects not listed in this leaflet. Also report side effects directly to the Yellow Card Scheme even if you think they are unrelated to this medicine.

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

5. HOW TO STORE ACICLOVIR FOR INFUSION

Aciclovir for infusion must be kept out of the reach of children.

Do not use this medicine past the expiry date shown on the packaging. If you use a medicine past the expiry date, it may have no further effect. Aciclovir for infusion is a sensitive product which can be affected by light. The outer white plastic cover should be kept in the dark and the bottle stored in the refrigerator.

Do not use a medicine which looks or smells different from the original.

This medicine should be disposed of by the household waste or the medical waste system.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK Only)

Please be ready to give the following information:
Product Name
Aciclovir 250mg Powder for Solution for Infusion
Reference Number
293110320

This is a service provided by the Royal National Institute of Blind People.

Marketing Authorisation holder and manufacturer
Wockhardt UK Limited, 60-64 East Road, North Woolwich, London, E16 3UR, UK.

This leaflet was last revised in April 2015

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6. FURTHER INFORMATION

What Aciclovir for infusion contains
Aciclovir for infusion contains aciclovir, sodium (the sodium salt), as a powder. The other ingredients are sodium hydroxide.

What Aciclovir for infusion looks like and contents of the pack
Each vial contains 250 mg of aciclovir as a sodium salt (baclofen salt). It is available in packs of (10) or (5) vials.

Not all pack sizes may be marketed.

Other formats

7. PHARMACEUTICAL PARTICULARS

6.1. List of ingredients

Aciclovir 250 mg

6.2. List of excipients

Aciclovir 250 mg

6.3. Dosage and administration

Aciclovir 250 mg

6.4. Special precautions for storage

Aciclovir 250 mg

6.5. Nature and contents of container

Aciclovir 250 mg

6.6. Instructions for use and handling

Aciclovir 250 mg

7. MARKETING AUTHOREISATION HOLDER

Aciclovir 250 mg

8. MARKETING AUTHORISATION NUMBERS

Aciclovir 250 mg

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Aciclovir 250 mg

10. DATE OF REVISION OF THE TEXT

Aciclovir 250 mg