

Rx

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

Aciclovir Intravenous Infusion IP 500 mg

PRIMA VIR™-500

Composition:

Each vial contains:

Aciclovir IP 500 mg
(As Aciclovir Sodium Sterile)

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 or 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 ACYCLOVIR 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* infections (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 ACYCLOVIR

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.

3. HOW TO USE 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.

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

- 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 Effect :

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).

Storage : Store at a temperature not exceeding 30°C. Protect from light & moisture.

Keep the medicine out of reach of children.

5. HOW TO STORE ACYCLOVIR

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.

What Aciclovir looks like and contents of the pack

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

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(A WHO-GMP Certified Co.)

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