

PATIENT INFORMATION LEAFLET FOR ACYRAX I.V.

SCHEDULING STATUS OF ACYRAX I.V.

SCHEDULE 4

PROPRIETARY NAME AND DOSAGE FORM:

ACYRAX I.V. 250 mg aciclovir per 10 ml solution for infusion

Read all of this leaflet carefully before you start using **ACYRAX I.V.**

ACYRAX I.V. will be administered by a healthcare professional.

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

ACYRAX I.V. has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT ACYRAX IV CONTAINS

The active ingredient in **ACYRAX I.V.** is aciclovir.

The contents are 250 mg per 10 ml solution for infusion.

The product does not contain any preservatives or alcohol.

2. ACYRAX I.V. IS USED FOR:

The prevention and treatment of Herpes simplex infection genital herpes or cold sores in patients whose bodies are less able to fight infections.

ACYRAX I.V. is used to treat:

- Shingles, if the wounds are not older than 3 days

- Chickenpox
- Serious virus infections in children up to 3 months of age.
- Inflammation of the brain.

ACYRAX I.V. is used to prevent recurrence of serious viral infections in patients who tested positive for viral infections after bone marrow transplant.

3. BEFORE ACYRAX I.V. ADMINISTERED TO YOU:

ACYRAX I.V. should not be administered to you:

- If you are hypersensitive (allergic) to **ACYRAX I.V.**, valaciclovir or any the other ingredients used in **ACYRAX I.V.**
- If you are pregnant (see **Pregnancy and Breast-feeding**)

Tell your doctor or healthcare professional before being given ACYRAX I.V.

if you:

- have kidney or liver problems
- are over 65 years of age
- are breast-feeding.
- have a disease of the brain, spine or nerves that connect them
- have been told by a doctor that you have electrolyte imbalance

If you are not sure if the above applies to you, speak to your doctor or pharmacist.

Pregnancy and Breast-feeding

If you are breast-feeding, please inform your doctor as aciclovir does pass into breast milk and will be passed via the breast milk to your baby.

If you are pregnant while receiving **ACYRAX I.V.**, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery

ACYRAX I.V. may interfere with your ability to drive or operate any tools or machines safely. You should drive or operate tools or machines with caution.

Taking other medicines with ACYRAX I.V.:

Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines).

Inform your doctor, pharmacist or healthcare 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 from rejecting transplanted organs

4. HOW ACYRAX I.V. WILL BE ADMINISTERED TO YOU:

You will not be expected to give yourself **ACYRAX I.V.** It will be given to you by a person who is qualified to do so.

ACYRAX I.V. will be diluted in intravenous fluid for infusion into your veins.

It will be given slowly over a period of time.

The dose that you will be given, the frequency of administration and the duration of the dose will depend on:

- the type of infection you have
- your weight
- your age
- your kidney function.

It is important you receive plenty of fluids while you are being given **ACYRAX I.V.**

If you are given more ACYRAX I.V. than you should:

If you have been given too much **ACYRAX I.V.** you may:

- feel confused or agitated
- have hallucinations (seeing or hearing things that are not there)
- have fits
- become unconscious (coma).

Since a healthcare professional will administer **ACYRAX I.V.** he/she will control the dosage.

However, in the event of overdose your doctor will manage the overdose.

5. POSSIBLE SIDE EFFECTS

ACYRAX I.V. can have side effects.

Not all side effects reported for **ACYRAX I.V.** are included in this leaflet. Should your general health worsen while receiving **ACYRAX I.V.**, please consult your doctor, pharmacist or other healthcare provider for advice.

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

- rash, itching or hives on your skin
- swelling of your face, lips, tongue, throat or other parts of your body
- shortness of breath, wheezing or trouble breathing

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ACYRAX I.V.** You may need urgent medical attention or hospitalisation.

Other side effects include:

Frequent:

- feeling or being sick
- itchy, hive-like rash
- skin reaction after exposure to light (photosensitivity)
- itching
- inflammation of the leg or arm veins
- unexplained fever (high temperature) and feeling faint, especially when standing up.

Less frequent:

- nosebleeds and bruising more easily than usual.
- swelling, redness and tenderness at the site of injection.
- 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 are not 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).
- serious skin conditions e.g. Steven-Johnson Syndrome (severe blisters, peeling and open sores on the skin)

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

6. STORING AND DISPOSING OF ACYRAX I.V.

Store at or below 25 °C.

The diluted solution will be prepared immediately before use.

The diluted solution must not be refrigerated. Any unused portion will be discarded.

A new vial will be used for the next dose.

Do not use if the product is past its expiry date which is stated on the label.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN