

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a physician's prescription only

Zovirax I.V.

Powder for preparation of a solution for infusion

Each vial contains: aciclovir 250 mg/vial.

For the list of inactive and allergenic ingredients in the preparation, see section 2 – “Important information about some of the ingredients of the medicine” and section 6 – “Further information”.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Zovirax I.V. is indicated:

- for the treatment of *Herpes simplex* infections in immunocompromised patients and for the treatment of severe initial genital herpes in non-immunocompromised patients.
- for the prophylaxis of *Herpes simplex* infections in immunocompromised patients.
- for the treatment of chickenpox (*Varicella zoster*).
- to treat inflammation of the brain caused by the herpes virus (herpes encephalitis).
- for the treatment of *Herpes simplex* infections in neonates and infants up to 3 months of age.

Therapeutic group: Zovirax I.V. belongs to a group of medicines called antivirals.

Zovirax I.V. contains a medicine called aciclovir. It works by killing or stopping the growth of viruses.

2. BEFORE USING THE MEDICINE

Do not use Zovirax I.V. if:

- you are sensitive (allergic) to aciclovir or valaciclovir or to any of the additional ingredients contained in the medicine (listed in section 6).

Do not take Zovirax I.V. if this applies to you. If you are not sure, refer to the physician or pharmacist before taking Zovirax.

Special warnings regarding the use of the medicine

Before treatment with Zovirax I.V., tell the physician or pharmacist if:

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

If you are not sure if these apply to you, talk to your physician or pharmacist before taking Zovirax I.V.

It is important that you drink plenty of water while taking Zovirax I.V.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines, herbal medicines and nutritional supplements, tell the physician or the pharmacist.

Especially if you are taking:

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, consult the physician or pharmacist before using this medicine.

Driving and operating machinery

This medicine is usually given during hospitalization and therefore, the effect on driving and operating machinery is usually not relevant.

No studies on the effect of aciclovir on driving and operating machinery have been conducted.

Important information about some of the ingredients of the medicine

Zovirax I.V. contains 28.03 mg sodium (the main ingredient of cooking/table salt) per vial. This is equivalent to 1.4% of the recommended maximum daily dietary intake of sodium for adults.

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

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by a physician only.

How the medicine is administered

You will not be expected to give yourself this medicine. The medicine will always be given to you by a person who is trained to do so.

The medicine will be diluted before being given.

Zovirax I.V. will be given to you as a continuous infusion into the vein. This is

how the drug is slowly given over a period of time.

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

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

The physician may adjust the dose of Zovirax I.V. if:

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

If this applies to you, talk to your physician before receiving Zovirax I.V.

Do not exceed the recommended dose.

If you received too much Zovirax I.V.

If you think you have been given too much Zovirax I.V., talk to the physician or nurse immediately.

If you have been given too much Zovirax I.V., you may:

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

If a child has accidentally swallowed the medicine, refer immediately to a physician or proceed to a hospital emergency room and bring the package of the medicine with you.

Adhere to the treatment regimen as recommended by the physician.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Zovirax I.V. may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Allergic reactions (these may occur in up to 1 in 10,000 people)

If you have an allergic reaction, **stop taking Zovirax I.V. and refer to physician immediately.** The signs may include:

- rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or trouble breathing
- unexplained fever (high temperature) and feeling faint, especially when you stand up.

Additional side effects

Common side effects (these may occur in up to 1 in 10 people)

- nausea or vomiting
- itchy, hive-like rash
- skin reaction after exposure to light (photosensitivity)
- itching
- swelling, redness and tenderness at the injection site
- increased liver enzymes.

Uncommon side effects (these may occur in up to 1 in 100 people)

- reduced numbers of red blood cells (anemia)
- reduced numbers of white blood cells (leukopenia)
- reduced numbers of blood platelets (cells that help the blood clot) count (thrombocytopenia).

Very rare side effects (these may occur in up to 1 in 10,000 people)

- headache or feeling dizzy
- diarrhea or stomach pains
- feeling tired
- fever
- effects on certain blood and urine tests
- feeling weak
- feeling agitated or confused
- shaking or tremors
- hallucinations (seeing or hearing things that do not exist)
- 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 behavior, 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 the lower back, the kidney area of the back or above the hip (renal pain).

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult the physician.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link:

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (Exp. date) appearing on the carton. The expiry date refers to the last day of that month.
- Store below 25°C.
- Prepare immediately before use.
- Discard solution that was not used.
- Do not discard any medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
Sodium hydroxide.
Also see section 2 in the leaflet – “Important information about some of the ingredients of the medicine”.
- What the medicine looks like and the content of the package:
Zovirax I.V. is supplied in glass vials containing an off-white powder.
The package contains 5 vials, each with a volume of 17 ml.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Manufacturing S.p.A., Pharma, Italy.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 034-33-21976

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