Package leaflet: Information for the user

Zovirax® I.V. 250 mg and 500 mg aciclovir

Read all of this leaflet carefully before you start having 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 pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed
 in this leaflet. See section 4.

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1 What Zovirax is and what it is used for

Zovirax I.V. (called 'Zovirax' in this leaflet) contains a medicine called aciclovir. This belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses.

Zovirax 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 What you need to know before you have Zovirax

Do not have Zovirax:

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

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

Warnings and precautions

Talk to your doctor or pharmacist before having Zovirax 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 Zovirax.

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

Other medicines and Zovirax

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal 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.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Zovirax contains sodium

Zovirax contains 26 mg sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

3 How to have Zovirax

How your medicine is given

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.

Zovirax 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 Zovirax if:

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

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

If you are given too much Zovirax

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

If you have been given too much Zovirax you may:

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

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

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

If you have an allergic reaction, stop taking Zovirax 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).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Zovirax

- Keep this medicine out of the sight and reach of children.
- Store below 25°C.
- Do not use Zovirax after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.
- Prepare immediately before use.
- Discard unused solution.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Zovirax I.V. contains

- The active substance is aciclovir.
- The other ingredient is sodium hydroxide.

What Zovirax looks like and contents of the pack

Zovirax I.V. is supplied in glass vials, containing an off-white powder. The 250 mg strength is available in 17 ml vials, in a box containing 5 vials. The 500 mg strength is available in 24 ml vials, in a box containing 5 vials.

Marketing authorisation holder and manufacturer

Marketing authorisation holder

The Wellcome Foundation Ltd, Stockley Park West, Uxbridge, Middlesex, UB11 1BT

Manufacturer

GlaxoSmithKline Manufacturing S.p.A., Parma 43056, Italy

Other formats:

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 Zovirax I.V. 250 mg

Zovirax I.V. 500 mg

Reference number 00003/0159

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

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