

ZOVIRAX IV

Patient Information Leaflet

SCHEDULING STATUS:

S4

ZOVIRAX IV Injection

Acyclovir 250 mg per vial

Read all of this leaflet carefully before you are given ZOVIRAX IV.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ZOVIRAX IV has been prescribed for you personally and you should not pass it on to others.
It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What ZOVIRAX IV is and what it is used for
2. What you need to know before you use ZOVIRAX IV
3. How to use ZOVIRAX IV
4. Possible side effects
5. How to store ZOVIRAX IV
6. Contents of the pack and other information.

1. What ZOVIRAX IV is and what it is used for:

ZOVIRAX is an antiviral agent.

ZOVIRAX is used to treat herpes encephalitis, shingles and chicken pox.

ZOVIRAX is also used to treat herpes simplex infections and to prevent recurrent attacks of herpes simplex infections in people whose immune systems are weakened.

ZOVIRAX prevents a virus called cytomegalovirus (CMV) in people who have had a bone marrow transplant.

2. What you need to know before you use ZOVIRAX IV:

ZOVIRAX IV should not be administered to you:

- if you have an allergy to, or if you have previously experienced an allergic reaction to acyclovir, or valaciclovir.

Warnings and precautions:

Take special care with ZOVIRAX IV:

Tell your doctor or healthcare provider before being given the injection if:

- you are pregnant or trying to become pregnant
- you are breastfeeding or planning to breastfeed
- you suffer from kidney or liver disease
- if you are elderly.

If you are elderly or if you have kidney problems, it is important that you drink adequate fluids whilst you are having treatment. The doctor will monitor you closely as there is a risk of experiencing nervous system side effects (see section 4).

If any of the above applies to you or if you are unsure if they apply to you, and if you have not already discussed with your doctor, tell your doctor or pharmacist before you start using ZOVIRAX.

Other medicines and Zovirax IV:

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

Take special care with ZOVIRAX IV if you are taking any of the following medicines: probenecid, cimetidine or mycophenolate mofetil (immunosuppressant agent used in kidney transplants).

Pregnancy, breastfeeding and fertility:

You should not breastfeed your baby if you are on treatment with ZOVIRAX IV.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before you are given ZOVIRAX.

3. How to use ZOVIRAX IV:

You will not be expected to give yourself ZOVIRAX IV.

It will always be given to you by a healthcare worker who is qualified to do so.

Your doctor will prescribe a dose to suit you or your child, depending on your condition and your response to this treatment.

ZOVIRAX IV injection will be reconstituted before use and will be given to you by slow intravenous infusion over a one hour period.

If you are given more ZOVIRAX IV than you should:

Since a healthcare provider will administer ZOVIRAX IV, he/she will control the dosage.

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

If you have been given too much ZOVIRAX IV, you may:

- feel confused and agitated
- see or hear things that are really not there (hallucinations)

- have fits (seizures)
- become unconscious (coma).

If you forget to take ZOVIRAX IV:

Since a healthcare provider will administer ZOVIRAX IV, it is unlikely that the dose will be missed.

4. POSSIBLE SIDE EFFECTS:

ZOVIRAX IV can have side effects.

Not all side effects reported for ZOVIRAX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ZOVIRAX, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, tell your doctor immediately:

- severe allergic reaction symptoms which include sudden wheeziness, fluttering or tightness of the chest, collapse, swelling of the eyelids, face lips or elsewhere, skin rash or weals.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZOVIRAX. You may need urgent medical attention.

Tell your doctor if you experience any of the following side effects:

Frequent side effects:

- feeling or being sick
- itching and mild skin reactions e.g. hives/nettle rash or skin rashes (including a skin reaction after exposure to sunlight)
- effects on some blood and urine tests.

Less frequent side effects:

- weakness, tiredness, feeling faint or shortness of breath. These symptoms may mean you have reduced number of red blood cells (anaemia)
- although you may not notice any symptoms, ZOVIRAX may cause a decrease in your white blood cells
- bruising or nose bleeds. These symptoms mean you have a low number of platelets, a type of white blood cell
- severe allergic reaction symptoms which include sudden wheeziness, fluttering or tightness of the chest, collapse, swelling of the eyelids, face lips or elsewhere, skin rash or weals.

These symptoms may mean that you or your child, are allergic to ZOVIRAX. Check with your doctor immediately if you experience any of these symptoms so that he/she can take the correct action

- headache, dizziness, agitation, confusion, agitation, shakiness, irregular body movements, difficulties with speech, hallucinations, fits, sleepiness during the day, loss of contact with reality
- difficulty breathing
- diarrhoea and stomach pains
- liver problems, or yellowing of the skin and the whites of the eyes, impaired kidney function or kidney failure
- fatigue, fever, localised swelling and redness around the injection site
- pain in the flank/kidney area of your back.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ZOVIRAX IV.

5. How to store ZOVIRAX IV:

Store all medicines out of reach of children.

Store at or below 25 °C.

The doctor or nurse must give you ZOVIRAX IV immediately after they have mixed it with the diluent and they will discard any excess/medicine that has not been given. Reconstituted or diluted solution should not be refrigerated.

The doctor or nurse will make sure that ZOVIRAX IV will not be given to you if it has passed the expiry date.

6. Contents of the pack and other information:

What ZOVIRAX IV contains:

Each vial contains the active substance acyclovir 250 mg as the sodium salt.

Each vial contains approximately 26 mg of sodium.

There are no other ingredients in ZOVIRAX IV injection.

What ZOVIRAX IV looks like and contents of the pack:

Vial containing a white to off-white powder.

Carton containing 5 clear, colourless glass vials.

Holder of Certificate of Registration and Manufacturer:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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