

ZOVIRAX IV

Approved Patient Information Leaflet

Read all of this leaflet carefully before ZOVIRAX IV is administered to you.

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

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

ZOVIRAX 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.

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

ZOVIRAX IV Injection

COMPOSITION OF ZOVIRAX IV, THAT IS, WHAT ZOVIRAX IV CONTAINS:

Each vial contains acyclovir 250 mg as the sodium salt.

Each vial contains approximately 26 mg of sodium.

There are no other ingredients in ZOVIRAX IV injection.

APPROVED INDICATION AND USE, THAT IS, WHAT ZOVIRAX IV 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.

INSTRUCTIONS BEFORE ZOVIRAX IV IS ADMINISTERED TO YOU:

You should not receive ZOVIRAX IV if:

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

Before ZOVIRAX IV is administered to you, tell your doctor 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 taking any of the following medicines: probenecid, cimetidine or mycophenolate (immunosuppressant agent used in kidney transplants).

If you answer yes to any of the above questions, 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.

Always tell your health care professional if you are taking any other medicine.

If you are pregnant or breast feeding your baby please consult your doctor, pharmacist or other health care professional for advice before using this medicine.

INSTRUCTIONS ON HOW ZOVIRAX IV IS TO BE ADMINISTERED:

Do not share medicines prescribed for you with any other person.

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.

If you are elderly or if you have kidney problems, your dosage may be adjusted and 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 SIDE EFFECTS).

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

SIDE EFFECTS:

You may experience side effects with ZOVIRAX IV. Tell your doctor if you experience any of the following side effects:

The most common side effects include:

- 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.

Uncommon side effects include:

- 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.

Very rare side effects include:

- 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 wheals. **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.

If you or your child suffer from any of the above side effects which are causing you concern, or if you notice any other side effect that is not listed above, tell your doctor or nurse.

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 health care professional for advice.

STORAGE AND DISPOSAL INFORMATION:

Store all medicines out of the reach of children.

Store below 25 °C.

The doctor or nurse must give you this medicine 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 this medicine will not be given to you if it has passed the expiry date.

PRESENTATION:

Carton containing 5 clear, colourless glass vials.

IDENTIFICATION:

Vial containing a white to off-white powder.

REGISTRATION NUMBER:

Q/20.2.8/164

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF**REGISTRATION:**

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

Date of last approval: 02 March 2013

Date compliant with Regulation 10: 12 March 2015