ZOVIRAX Oral Range

Patient Information Leaflet

SCHEDULING STATUS:

S4

ZOVIRAX 200 Dispersible Tablets

Aciclovir 200 mg per dispersible tablet

Sugar-free

ZOVIRAX SUSPENSION

Aciclovir 200 mg per 5 ml suspension

Contains sugar (sorbitol 2 250 mg/5 ml)

Read all of this leaflet carefully before you start taking ZOVIRAX.

- 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 share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1. What ZOVIRAX is what it is used for:

Aciclovir (the active ingredient of ZOVIRAX) belongs to a group of medicines called antivirals. ZOVIRAX works by stopping the production of the virus.

This reduces the length and severity of an outbreak of infection. ZOVIRAX does not get rid of the virus from your body.

ZOVIRAX can be used to:

- treat chickenpox and shingles
- treat cold sores, genital herpes and other herpes simplex infections
- stop cold sores, genital herpes and other herpes virus infections from coming back after you have had them
- prevent herpes virus infections in people whose immune systems work less well, which means their bodies are less able to fight infections.

2. What you need to know before you take ZOVIRAX:

You should not take ZOVIRAX:

- if you have an allergy to, or if you have previously experienced an allergic reaction to aciclovir, or valaciclovir, or to any of the ingredients of ZOVIRAX (listed in section 6).

Warnings and precautions:

Take special care with ZOVIRAX:

Before you start taking ZOVIRAX, tell your doctor if:

- you are pregnant or intend to become pregnant
- you are breastfeeding or planning to breastfeed
- you have a kidney or liver condition
- if you are elderly.

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 taking ZOVIRAX.

Other medicines and ZOVIRAX:

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

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

Pregnancy, breastfeeding and fertility:

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

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

Driving and using machines:

Some side effects such as feeling drowsy or sleepy may impair your ability to concentrate and react. Make sure you are not affected before you drive or operate machinery.

ZOVIRAX SUSPENSION contains sorbitol:

Sorbitol may have a laxative effect.

If you have been told that you have an intolerance to some sugars, you should not take ZOVIRAX SUSPENSION.

3. How to take ZOVIRAX:

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

Always take ZOVIRAX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will decide on the correct dose to take, how often and for how long, depending on:

- the type of infection you have
- whether it is to treat the infection or to stop it coming back.

Your doctor will be monitoring you closely as there is a risk of you experiencing nervous system side effects (see section 4).

It is important that you drink adequate fluids whilst you are having treatment.

If you have the impression that the effect of ZOVIRAX is too strong or too weak, tell your doctor of pharmacist.

If you take more ZOVIRAX that you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of ZOVIRAX:

Take one dose as soon as you remember and then take the next dose at the correct time. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects:

ZOVIRAX 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 taking ZOVIRAX, please consult your doctor, pharmacist of other healthcare professional for advice.

If any of the following happens, stop taking ZOVIRAX and tell your doctor immediately or go to the casualty department at your nearest hospital.

- severe allergic reaction symptoms which include, sudden wheeziness, fluttering or tightness in the chest, collapse, swelling of 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 or hospitalisation.

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

Frequent side effects include:

- headache, dizziness
- feeling or being sick (nausea, vomiting), diarrhoea and stomach cramps
- itching, skin rashes (including a skin reaction after exposure to sunlight)
- fever and feeling tired.

Less frequent side effects include:

- mild skin reactions e.g., hives/nettle rash
- hair loss
- severe allergic reaction symptoms which include, sudden wheeziness, fluttering or tightness in the chest, collapse, swelling of eyelids, face, lips or elsewhere, skin rash or weals. Check with your doctor immediately if you or your child experiences any of these severe symptoms. **These symptoms may mean that you or your child, are allergic to ZOVIRAX.** Do NOT take any more of this medicine unless your doctor has advised you to do so
- difficulty breathing
- effects on some blood and urine tests. Let the doctor know that you are taking ZOVIRAX if you are having a blood or urine test
- liver problems, or yellowing of the skin and the whites of the eyes
- impaired kidney function or kidney failure

- 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, this medicine 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
- agitation, confusion, shakiness, irregular body movements, difficulties with speech, hallucinations, fits, drowsiness, sleepiness during the day, loss of contact with reality
- 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.

5. How to store ZOVIRAX:

Store all medicines out of reach of children.

Protect from light.

ZOVIRAX 200 Dispersible Tablets: Store at or below 30 °C and in dry place.

ZOVIRAX SUSPENSION: Store at or below 25 °C.

Do not use if the expiry date on the packaging has passed. If you take ZOVIRAX after the expiry date has passed, it may not work as well.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information:

What ZOVIRAX contains:

Each ZOVIRAX 200 Dispersible Tablet contains 200 mg of the active substance aciclovir.

Sugar-free.

The inactive ingredients include aluminium magnesium silicate, magnesium stearate, microcrystalline cellulose, povidone K30 and sodium starch glycollate. The film coat contains hypromellose, polyethylene glycol and titanium dioxide.

Each 5 ml of ZOVIRAX SUSPENSION contains 200 mg of the active substance aciclovir, methyl hydroxybenzoate 0,1 % *m/v* and propyl hydroxybenzoate 0,02 % *m/v* (as preservatives).

Contains sugar (sorbitol 2 250 mg/5 ml).

The inactive ingredients include Avicel, banana flavourant, glycerol, purified water and vanillin.

What ZOVIRAX looks like and contents of the pack:

ZOVIRAX 200 Dispersible Tablets:

White, round, biconvex, film-coated tablets, branded ‘GXCF3’ on one side and plain on the other side.

ZOVIRAX Dispersible tablets are packed in polyvinyl chloride (PVC)/polyvinylidene chloride (PVdC)/Aluminium foil blister packs or in PVC/PVdC/Aluminium/Paper Child Resistant foil blister packs each containing 25 tablets.

ZOVIRAX SUSPENSION:

An off-white, viscous suspension with a banana odour and taste.

Amber glass bottles of 125 ml.

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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