SCHEDULING STATUS S4

VALATREX 250 (film-coated tablets)

VALATREX 500 (film-coated tablets)

Please read this leaflet carefully before using VALATREX

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine 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 VALATREX is and what it is used for
2. What you need to know before taking VALATREX
3. How to take VALATREX
4. Possible side effects
5. How to store VALATREX
6. Contents of the pack and other information

1. WHAT VALATREX IS AND WHAT IT IS USED FOR

VALATREX contains the active substance valaciclovir.

The active ingredient, valaciclovir, is an antiviral agent. It specifically acts on herpes viruses.

Herpes zoster (shingles):

VALATREX reduces the pain associated with shingles, the duration thereof and the persistence of pain after an attack.

Herpes simplex:

Episodes of recurrent genital herpes in adults with normal immune systems.

Prevention (suppression) of recurrent Herpes simplex infection of the skin and mucous membrane of the ano-genital area.

Cytomegalovirus (CMV):

Prevention of CMV and other herpes virus infections and disease after organ transplantation, where special risks exist.

2. WHAT YOU NEED TO KNOW BEFORE TAKING VALATREX

Do not take VALATREX:

- If you are hypersensitive (allergic) to valaciclovir, aciclovir or any of the other ingredients of VALATREX (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before take VALATREX if

- you have kidney problems
- you have liver problems
- you are over 65 years of age
- your immune system is weak.

Other medicines and VALATREX

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

Tell your doctor or pharmacist if you are taking any other medicines that affect the kidneys. These include: aminoglycosides, organoplatinum compounds, iodinated contrast media, methotrexate, pentamidine, foscarnet, ciclosporin, tacrolimus, cimetidine and probenecid.

Always tell your doctor or pharmacist about other medicines if you are taking VALATREX for treatment of shingles or after having an organ transplant.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding your baby while taking VALATREX, please consult your doctor, pharmacist or other healthcare professional for advice.

Safety in pregnancy has not been established.

Driving and using machines:

Be careful of driving or operating machines until you know how VALATREX affects you. Side effects such as drowsiness and sleepiness are possible when taking VALATREX and these could affect your ability to drive or operate machines.

3. HOW TO TAKE VALATREX

Always take VALATREX 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 appropriate dose and duration of treatment for your condition.

Dosage in adults:

If you suffer from kidney disease, please consult your doctor for information on how to take VALATREX.

Dosage for elderly patients:

The dosages as prescribed by your doctor are recommended, your doctor may adjust the dosage if you suffer from kidney function problems.

If you have the impression that the effect of VALATREX is too strong or too weak, talk to your doctor or pharmacist.

Do not chew the tablets, but swallow with an adequate amount of water. Also ensure that enough liquids are taken during the day.

If you take more VALATREX than you should:

In the event of overdosage (if you take more VALATREX than recommended), consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison center.

If you forget to take VALATREX:

The moment you remember about it, take the dose immediately, unless it is nearly time for the next dose.

Do not take a double dose to make up for forgotten individual doses. If in doubt, consult your doctor or pharmacist for advice.

4. POSSIBLE SIDE EFFECTS

VALATREX can have side effects.

Not all side effects reported for VALATREX are included in this leaflet. Should your general health worsen while taking VALATREX, please consult your doctor, pharmacist or other healthcare professional for advice.

If you get any of the following side effects, tell your doctor immediately, or contact the casualty department at your nearest hospital

- severe allergic reactions (anaphylaxis). These are rare in people taking VALATREX. Rapid development of symptoms including:
- flushing, itchy skin rash
- swelling of the lips, face, neck and throat, causing difficulty in breathing (angioedema)
- fall in blood pressure leading to collapse.

If you have an allergic reaction, stop taking VALATREX and see a doctor straight away.

The following side effects were reported frequently:

headache

- feeling sick
- dizziness
- vomiting
- diarrhoea
- skin reaction after exposure to sunlight (photosensitivity)
- rash

itching (pruritus).

The following side effects were reported less frequently:

feeling confused

- seeing or hearing things that aren't there (hallucinations)

- feeling very drowsy
- Tremors
- feeling agitated
- shortness of breath (dyspnoea)
- stomach discomfort
- rash, sometimes itchy, hive-like rash (urticaria)
- low back pain (kidney pain)
- blood in urine (haematuria)
- reduction in the number of white blood cells (leucopenia)
- reduction in the number of blood platelets which are cells that help blood to clot (thrombocytopenia)
- increase in substances produced by the liver
- unsteadiness when walking and lack of coordination (ataxia)
- slow, slurred speech (dysarthria)
- fits (convulsions)
- altered brain function (encephalopathy)
- unconsciousness (coma)
- confused or disturbed thoughts (delirium)
- kidney problems where you pass little or no urine.

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of VALATREX a day. They usually get better when VALATREX is stopped or the dose reduced.

Reporting of side effects

If you get side effects, talk to your doctor, 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 VALATREX.

Suspected side effects can also be reported directly to the Holder of certificate of registration via Patientsafety.sacg@novartis.com.

5. HOW TO STORE VALATREX

Store at or below 30 °C, in the original cardboard carton.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

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

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What VALATREX contains:

- Each Valatrex 250 mg tablet contains valaciclovir hydrochloride monohydrate equivalent to 250 mg valaciclovir.
- Each Valatrex 500 mg tablet contains valaciclovir hydrochloride monohydrate equivalent to 500 mg valaciclovir.

Sugar free.

Inactive ingredients:

Crospovidone, microcrystalline cellulose, povidone, magnesium stearate and Opadry white (coating ingredient).

What VALATREX looks like and contents of the pack

Valatrex 250: White to off-white capsule shaped film-coated tablets plain on both sides.

Valatrex 500: White to off-white capsule shaped film-coated tablets with “500” debossed on one side and plain on other side.

Valatrex 250: Aluminium foil / trilaminate (PVC/PE/PVDC) blister packs of 60 tablets.

Valatrex 500: Aluminium foil / trilaminate (PVC/PE/PVDC) blister packs of 42, 30 and 10 tablets.

The Alu/trilaminate PVC blister strips are packed into a cardboard carton.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Waterfall 5-Ir

Magwa Crescent West

Waterfall City

Jukskei View

2090

This leaflet was last revised in

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Registration numbers

Valatrex 250: 42/20.2.8/0340

Valatrex 500: 42/20.2.8/0341

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07