

ZELITREX® Tablets

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME STRENGTH AND PHARMACEUTICAL FORM:

ZELITREX® 250 Tablets

ZELITREX® 500 Tablets

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ZELITREX 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. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

WHAT ZELITREX CONTAINS:

Each ZELITREX 250 tablet contains 250 mg valaciclovir.

Each ZELITREX 500 tablet contains 500 mg valaciclovir.

The tablet cores also contain the following inactive ingredients:
microcrystalline cellulose, crospovidone, povidone K90, magnesium stearate and colloidal anhydrous silica.

The 250 mg tablet film-coat contains hydroxypropylmethylcellulose, titanium dioxide, polyethylene glycol 400.

The 500 mg tablet film coat contains hydroxypropylmethylcellulose, titanium dioxide, polyethylene glycol 400, polysorbate 80 and blue printing ink.

WHAT ZELITREX IS USED FOR:

ZELITREX is a prescription antiviral medicine. ZELITREX works by killing or stopping the growth of herpes simplex (HSV), varicella zoster (VZV) and cytomegalovirus (CMV).

ZELITREX is used:

- to treat shingles (also called herpes zoster) in adults
- to treat or control genital herpes outbreaks in adults
- to treat and prevent recurrent herpes simplex infections of the skin e.g. cold sores
- to prevent infection with CMV after organ transplants in adults.

ZELITREX can be used for other conditions not mentioned above.

BEFORE YOU TAKE ZELITREX:

Do not take ZELITREX if:

- you have an allergy to acyclovir, valaciclovir, or to any of the inactive ingredients.

Take special care with ZELITREX:

Before you start taking ZELITREX, tell your doctor if:

- you have had a bone marrow transplant or kidney transplant, or if you have advanced HIV disease or AIDS. Patients with this condition have a higher chance for getting a blood disorder, (thrombotic, thrombocytopenic purpura/haemolytic uremic syndrome) which can result in death
- you have kidney problems
- you are elderly (65 years of age or older)
- you have liver problems.

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 taking ZELITREX.

Pregnancy and breastfeeding:

You should not use ZELITREX if you are pregnant or breastfeeding your baby. If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professional for advice before taking ZELITREX.

Driving and using machinery:

ZELITREX can cause side effects that affect your ability to drive.

- Do not drive or use machines unless you are sure you are not affected.

Taking other medicines with ZELITREX:

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

If you are taking other medicines on a regular basis, including medicines obtained without a prescription, the use of ZELITREX with these medicines may cause undesirable interactions.

Tell your doctor or pharmacist if you are taking any other medicines that affect the kidneys. These include cyclosporin, tacrolimus, cimetidine and probenecid.

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

Prevent passing genital herpes on to others:

Genital herpes is a sexually transmitted disease. You can spread genital herpes to others, even when you have no symptoms. If you are sexually active, you can still pass herpes to your partner, even if you are taking ZELITREX. Do not have sexual contact with your partner when you have any genital sores or blisters. You should use a condom made of latex or polyurethane whenever you have sexual contact.

HOW TO TAKE ZELITREX:

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

Always take ZELITREX exactly as your doctor has told you. The dose of ZELITREX and duration of treatment will depend on why your doctor has prescribed ZELITREX for you. Your doctor will discuss this with you.

It is important while you are taking ZELITREX that you drink water regularly. This will help to reduce side effects that can affect the kidney or the nervous system. Your doctor will closely monitor you for the signs of these. Nervous system side effects might include feeling confused or agitated, or feeling unusually sleepy or drowsy.

Swallow the tablets whole with a glass of water.

Your doctor may adjust the dose of ZELITREX if:

- you are over 65 years of age
- you have a weak immune system
- you have kidney problems.

Talk to your doctor before taking ZELITREX if any of the above apply.

If you take more ZELITREX than you should:

If you take too many tablets you may feel sick, vomit, or be confused, agitated or unusually sleepy. In the event of over dosage consult your doctor or pharmacist. If neither is available, contact

the nearest hospital or poison control centre. Take the medicine pack with you.

If you forget to take ZELITREX:

- If you forget to take ZELITREX, take it as soon as you remember. However if it is nearly time for your next dose, skip the missed dose.
- Don't take a double dose to make up for a forgotten dose.

POSSIBLE SIDE EFFECTS:

The following side effects may happen with ZELITREX:

Conditions you need to look out for:

- severe allergic reactions (anaphylaxis). These are rare in people taking ZELITREX. 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 ZELITREX and see your doctor immediately or go to the nearest hospital.

Frequent:

- headache

Nervous system side effects include:

- dizziness

- feeling confused
- seeing or hearing things that aren't there (hallucinations)
- feeling very drowsy
- tremors
- feeling agitated
- unsteadiness when walking and lack of coordination (ataxia)
- slow and slurred speech (dysarthria)
- fits (convulsions)
- altered brain function (encephalopathy)
- unconsciousness (coma)
- confused or disturbed thoughts.

These side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of ZELITREX.

Other side effects include:

- shortness of breath (dyspnoea)
- stomach discomfort, being sick (vomiting), diarrhoea
- rashes including skin reaction after expose to sunlight (photosensitivity), sometimes an itchy hive-like rash (urticaria)
- loss of kidney function or even kidney failure and lower back pain (kidney pain) and other kidney problem e.g. when you pass little or no urine.

Other side effects that may show up in your blood tests:

- reduction in the number of white blood cells (leukopenia)
- reduction in the number of blood platelets which are cells that help your blood clot (thrombocytopenia)
- increases in liver enzymes.

If you 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 pharmacist.

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

STORAGE AND DISPOSING OF ZELITREX:

Store all medicines out of reach of children.

Store the tablets at or below 30 °C.

Keep the tablets dry and protect from light.

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

PRESENTATION OF ZELITREX:

ZELITREX 250: Blister pack of 60 tablets

ZELITREX 500: Blister packs of 42 tablets

Blister packs of 30 tablets

Blister packs of 10 tablets

IDENTIFICATION OF ZELITREX:

ZELITREX 250:

Biconvex, elongated, white film-coated tablet with a white to off-white core. Unscoored and branded GXCE7 by engraving.

ZELITREX 500:

Biconvex, elongated, white film-coated tablet with a white to off-white core. Unscoored and branded GXCF1 and printed with blue-green or blue ink.

REGISTRATION NUMBER:

ZELITREX 250: 32/20.2.8/0465

ZELITREX 500: 29/20.2.8/0442

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

LITHA PHARMA (PTY) LTD

106 16th Road

Midrand

1685

South Africa

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GDS 20

History:

Amended: 16 March 2001

Amended: 17 February 2011 (To include new safety info GDS Versions 7 – 20)

Compliant response to CCC recommendation dated 8 April 2013.

Final Proposed Package Insert 8 August 2013

Approved by MCC 2013 12 06

25.06.2015 – Notification of implementation of Reg 9 & 10