Approved Proposed Patient Information Leaflet for EPITOZ 25 / 50 / 100

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

EPITOZ 25 / 50 / 100 film-coated tablets

Topiramate

Contains sugar (lactose):

EPITOZ 25: Contains 27,5 mg lactose per tablet.

EPITOZ 50: Contains 55,0 mg lactose per tablet.

EPITOZ 100: Contains 110,0 mg lactose per tablet.

Read this leaflet carefully before you start taking EPITOZ.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- EPITOZ 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 EPITOZ is and what it is used for
2. What you need to know before you take EPITOZ
3. How to take EPITOZ
4. Possible side effects
5. How to store EPITOZ

6. Contents of the pack and other information

1. What EPITOZ is and what it is used for

Topiramate the active ingredient of EPITOZ falls in the category of anticonvulsants. EPITOZ is used to help control some types of seizures in the treatment of epilepsy. In adults EPITOZ can be used on its own or in combination with other medicine to treat your epilepsy.
In children aged 4 years and over EPITOZ can be used in combination with other medicine to treat epilepsy.

2. What you need to know before EPITOZ is administered to you

Do not take EPITOZ:

- If you are allergic (hypersensitive) to topiramate or any of the other ingredients of EPITOZ (listed in section 6).
- If you are pregnant or breastfeeding your baby.
- EPITOZ should not be given to children under 2 years of age.

Warnings and precautions:

Tell your doctor before you take EPITOZ:

- If you have glaucoma (increased pressure in the eye). If you experience sudden blurring of vision, pain and redness of the eyes, typically during the first month of starting EPITOZ, you should tell your doctor immediately, as this can indicate glaucoma.
- If your kidney or liver function is impaired.
- If you have a history of kidney stones.

Take special care with EPITOZ and inform your doctor:

- If you have thoughts of inflicting harm to or killing yourself after starting your treatment with EPITOZ. If you have any thoughts of harming or killing yourself, contact your doctor or go to a

hospital immediately.

- If you start feeling depressed or if your mood changes while taking EPITOZ.
- If you experience visual field defect (a loss of part of your usual vision field) in either one of, or both your eyes.
- If you experience metabolic acidosis (a condition that occurs when your body produces excessive quantities of acid). Symptoms may include nausea, vomiting, fast breathing and lack of energy.
- If you or your child experience a decrease in sweating and increased body temperature (fever) while taking EPITOZ. People, especially children, should be watched for signs of decreased sweating and fever, especially in hot temperatures. Some people may need to be hospitalised for this condition. Call your doctor right away if you have a high fever, a fever that does not go away, or decreased sweating. It is important to drink enough fluids while taking EPITOZ. Drinking enough fluids while exercising or exposed to warm temperatures may reduce the risk of heat-related side effects.
- EPITOZ may cause high levels of ammonia in your blood (seen in blood tests) which can lead to a change in your brain function, especially if you are also taking a medicine called valproic acid (see “Other medicines and EPITOZ). If you develop symptoms such as difficulty thinking, difficulty remembering information or solving problems, feeling very sleepy with low energy, contact your doctor immediately.

You may lose weight while taking EPITOZ. Your weight should be checked regularly while taking EPITOZ. If you lose weight, you should consider a dietary supplement or increase your food intake.

Children and adolescents:

EPITOZ is indicated to treat epilepsy in children aged 4 years and over when used in combination with other anti-epileptic medicine (see “What EPITOZ is and what it is used for”). You should not give EPITOZ to your child if he is younger than 2 years of age.

Other medicines and EPITOZ:

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

Tell your doctor if you are using:

- Oral birth control pills (topiramate may cause for this birth control method to be ineffective).
- Phenytoin, carbamazepine, valproic acid, phenobarbital, primidone (used to treat epilepsy).
- Digoxin (used to treat heart failure and a fast heartbeat).
- Alcohol and medicine that suppress the central nervous system like sleeping tablets or medicine for anxiety.
- Amitriptyline, imipramine, moclobemide, St John's wort, (used to treat depression).
- Lithium (used to treat mania).
- Risperidone (used to treat psychosis, a severe mental disorder).
- Hydrochlorothiazide (used to remove excess water from your body).
- Metformin, pioglitazone, glyburide (used to treat high blood sugar levels).
- Warfarin (used to thin your blood).
- Propranolol and diltiazem (used to treat certain heart conditions).

EPITOZ with food, drink and alcohol:

You can take EPITOZ with or without food. Drink plenty of fluids during the day to avoid dehydration and prevent kidney stones while taking EPITOZ. You should avoid drinking alcohol when taking EPITOZ.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking EPITOZ.

Do not take EPITOZ if you are pregnant or breastfeeding.

Driving and using machines:

EPITOZ can cause dizziness, blurred vision and clumsiness. Do not drive or operate any machinery until you know how EPITOZ will affect your ability to drive or concentrate.

EPITOZ contains lactose:

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take EPITOZ.

3. How to take EPITOZ

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

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

The dose of EPITOZ will be different for different patients.

The number of doses you take each day, the time allowed between doses, and the length of time you take EPITOZ depend on the medical problem for which you are taking EPITOZ.

EPITOZ, unless otherwise prescribed, should be used as follows:

Adult dose:

When used in combination with other anti-epileptic medicines:

The usual starting dose is one EPITOZ 25 mg or 50 mg tablet taken once daily at bedtime for 1 week. Your doctor could further increase your dose depending on your response to treatment. He may advise you to take it in two divided doses.

When used as single therapy:

The usual starting dose is one EPITOZ 25 mg tablet taken once daily at bedtime for 1 week. Your

doctor may further increase your daily doses depending on your response to treatment.

Your dose may be different in case you have problems with your liver, your kidneys or if you are on haemodialysis.

Children 4 years and older:

The doctor will determine the correct dosage according to the child's body weight and specific condition.

Always swallow EPITOZ whole with plenty of water. It is important to drink plenty of water, especially if you exercise or the weather is hot (see "Warnings and precautions" above).

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

If you have taken more EPITOZ than you should:

In the event of overdosage, consult your doctor or pharmacist, if neither is available, seek help at the nearest hospital or poison control centre. Take this leaflet and the rest of the remaining tablets with you so the doctor will know what you have taken.

If you forget to take your EPITOZ:

Take the missed dose as soon as possible. However, if it is almost time for you next dose, continue to take the next tablet at the usual time. Do not take a double dose.

If you stop taking EPITOZ:

Do not suddenly stop taking EPITOZ without first checking with your doctor. Your epilepsy may return. If your doctor decides to stop EPITOZ, your dose may be decreased gradually over a few

days.

4. Possible side effects

EPITOZ can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.
- Severe peeling and blistering of the outer layers of the skin, potentially around the mouth, nose, eyes and genitals, or which can be widespread all over the body.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Visual disturbance, such as double vision, blurred vision, decreased vision, difficulty focusing, eye pain, uncontrolled back-and-forth movement of the eyes.
- Glaucoma which is a blockage of fluid in the eye causing increased pressure in the eye, pain and decreased vision.
- Slow or irregular heartbeat, feeling your heart beating in your chest.
- Low blood pressure, low blood pressure upon standing (consequently some people taking

EPITOZ may feel faint, dizzy or may pass out when they stand up or sit up suddenly).

- Depressed mood with thoughts of committing suicide.
- Hearing, seeing or feeling things that are not there, severe mental disorder.
- Difficulty thinking, remembering information, or solving problems, being less alert or aware, feeling very sleepy with low energy – these symptoms may be a sign of a high level of ammonia in the blood (hyperammonaemia), which can lead to a change in brain function (hyperammonaemic encephalopathy).
- Inflammation of the pancreas (pancreatitis), with symptoms such as severe stomach pain, nausea and vomiting.
- Involuntary shaking in the arms, hands or legs, increase in seizures (fits).
- Decreased or loss of hearing, deafness.
- Blood in urine, incontinence (lack of control of urine), urgent desire to urinate, flank or kidney pain, difficult or painful urination.
- Crystals in urine, kidney stones, with symptoms such as fever, chills and severe pain in the belly area, sides of the back, groin or testicles.
- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver inflammation or liver failure.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Reduced number of red blood cells.
- Weight loss, decrease in appetite.
- Weight increase.
- Depression, anxiety, changes in mood or behaviour (including aggression, nervousness, sadness, anger).
- Dizziness, sleepiness, feeling tired, tingling or pins and needles sensation.

- Changes in thinking and alertness, including confusion, problems with concentration, memory or slowness in thinking.
- Ringing sound in the ears, ear pain.
- Nausea, diarrhoea, vomiting, constipation, abdominal pain, indigestion, dry mouth.
- Tingling or numbness of the mouth.
- Runny nose, nose bleeds, shortness of breath.
- Cough.
- Hair loss (temporary).
- Joint pain, muscle spasms, muscle twitching or muscle weakness.
- Chest pain.
- Fever, loss of strength, general feeling of feeling unwell.

Less frequent side effects:

- Abnormal blood counts, including reduced white blood cell count or platelet count or increased eosinophils.
- Swollen glands in the neck, armpit or groin.
- Problems with verbal communication.
- Problems with coordination.
- Drooling, increased saliva flow.
- Restlessness or increased mental and physical activity.
- Impaired sense of smell, or loss of smell
- Problems with handwriting.
- Hoarseness of the voice.
- Bleeding gums.
- Fullness or bloating of the stomach, breath odour.
- Decrease or loss of sweating.
- Swelling.
- Muscle stiffness.

- Increased acid levels in the blood.
- Problems with learning.

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. You can also report side effects to SAHPRA via the "**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 EPITOZ.

5. How to store EPITOZ

Store at or below 25 ºC.

Keep the container tightly closed.

Protect from moisture.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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 EPITOZ contains:

The active ingredient is topiramate.

Each EPITOZ 25 tablet contains 25 mg topiramate.

Each EPITOZ 50 tablet contains 50 mg topiramate.

Each EPITOZ 100 tablet contains 100 mg topiramate.

The other ingredients are colloidal silicon dioxide, lactose anhydrous, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, Opadry White (containing hypromellose, titanium

dioxide, macrogol, talc).

What EPITOZ looks like and contents of the pack:

EPITOZ 25: White coloured, round shaped, biconvex, bevelled edge, film-coated tablets debossed with “ZD 16” on one side and plain on the other side.

EPITOZ 50: White coloured, round shaped, biconvex, bevelled edge, film-coated tablets debossed with “ZD 15” on one side and plain on the other side.

EPITOZ 100: White coloured, round shaped, biconvex, bevelled edge, film-coated tablets debossed with “ZD 14” on one side and plain on the other side.

The tablets should be free of all physical defects.

White polypropylene canister containing silica gel packed in a white HDPE (plastic) container with a white child-resistant polypropylene cap.

Or

White HDPE (plastic) container with a white polypropylene screw cap.

Pack size: 60 tablets.

Holder of certificate of registration and manufacturer:

Zydus Healthcare SA (Pty) Ltd

Southdowns Office Park

Building B, Ground Floor

22 Karee Street

Centurion, Pretoria

0157

Tel: 012 748 6400

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