PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 3

TOPALEX® 25 mg/ 50 mg/ 100 mg Tablets

Topiramate

Contains sugar (lactose monohydrate)

Each TOPALEX 25 mg tablet contains 30,85 mg lactose monohydrate

Each TOPALEX 50 mg tablet contains 61,70 mg lactose monohydrate

Each TOPALEX 100 mg tablet contains 123,40 mg lactose monohydrate

Read all of this leaflet carefully before you start taking TOPALEX tablets

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

1. What TOPALEX is and what it is used for

TOPALEX belongs to a group of medicines called antiepileptic medicines.

TOPALEX is used to treat various types of epilepsy.

TOPALEX may be used on its own to treat adults and children aged 2 years and over.

It can also be used in combination with other anti-epileptic medicines in both adults and children aged 4 years and over.

2. What you need to know before you take TOPALEX

Do not take TOPALEX:

- if you are hypersensitive (allergic) to topiramate or any of the ingredients of TOPALEX.
- if you are pregnant or think you may be pregnant.
- If you are breastfeeding as TOPALEX may reach your baby through your milk.
- TOPALEX should not be given to children under 2 years old.

Warnings and precautions

Talk to your doctor or pharmacist before taking TOPALEX

- Sudden blurring of vision, pain and redness of the eyes has occurred in both adults and children, typically during the first month of starting TOPALEX. This can indicate raised pressure within the eye (glaucoma). If you develop any eye symptoms, particularly in the first few weeks of treatment, you should tell your doctor immediately. If your doctor thinks you have raised pressure within the eye, he/she will advise you on how to stop taking TOPALEX and may refer you for specific eye treatment. You may also need to revisit your doctor to ensure your epilepsy is kept under control.
- If you are taking a contraceptive pill as well as TOPALEX and your menstrual bleeding patterns change (e.g. if you experience breakthrough bleeding, spotting or if you miss a period), consult your doctor.
- Blood tests may show an increase in acidity. Your doctor will monitor this, if necessary, and may adjust the amount of TOPALEX you are taking.
- It is important to drink plenty of water when taking TOPALEX especially if you are taking exercise or the weather is hot.
  If you, or a close relative, have ever had kidney stones, you have a greater risk for kidney stone formation, which may cause acute pain in the flank (side of the abdomen), and TOPALEX may increase this risk.
- You may notice a change in your mood, or experience feelings of depression while taking TOPALEX. Patients taking TOPALEX can sometimes have thoughts of harming themselves or taking their own lives. If you get these thoughts at any time, **contact your doctor or go to a hospital straight away**.
- TOPALEX can cause serious skin reactions, tell your doctor immediately if you develop

a skin rash (see also section 4 `Possible side effects').

- If you suffer from problems with your liver, please tell your doctor before taking
- TOPALEX. Your doctor may want to prescribe a lower dose.
- If you are losing weight or a child taking TOPALEX is not gaining enough weight, the amount of food being eaten should be increased.
  You may experience significant and continuing weight loss while taking TOPALEX. You should therefore be weighed and monitored regularly.
- You should be careful how much alcohol you drink while taking TOPALEX, or if you are taking any medicines that make you sleepy or less alert (these include tranquillisers, anti-depressants and sleeping pills), as the combined effect might make you feel less alert than usual.
- TOPALEX may cause decreased sweating and increased body temperature (fever). 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 healthcare provider right away if you have a high fever, a fever that does not go away, or decreased sweating.
- TOPALEX may in rare cases cause high levels of ammonia in the blood (seen in blood tests) which can lead to a change in brain function, especially if you are also taking a medicine called valproic acid or sodium valproate.
  Since this may be a severe condition, tell your doctor immediately if the following symptoms occur:
    - Difficulty thinking, remembering information, or solving problems
    - Being less alert or aware
    - Feeling very sleep with low energy

  At higher doses of TOPALEX, the risk of developing these symptoms may increase.

Other medicines and TOPALEX

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

Especially tell your doctor or pharmacist if you are taking:

- Other medicines that impair or decrease your thinking, concentration, or muscle coordination (e.g. central nervous system depressant medicines such as muscle relaxants and sedatives)
- Birth control pills TOPALEX may make your birth control pills less effective. You should talk to your doctor about the best kind of contraception to use.

Tell your doctor immediately if your menstrual bleeding changes while you are taking birth control pills and TOPALEX.

Other medicines you should discuss with your doctor or pharmacist include other anti-epileptic medicines, risperidone, lithium, hydrochlorthiazide, metformin, pioglitazone, glyburide, amitriptyline, propranolol, diltiazem, venlafaxine, flunaraizine, St. John's wort (a herbal preparation used to treat depression).

TOPALEX with food and drink

You can take TOPALEX with or without food.

Pregnancy and breastfeeding and fertility

If you are pregnant, trying to become pregnant or breastfeeding your baby while taking

TOPALEX, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine. It is recommended that women of childbearing potential use adequate contraception.

TOPALEX should not be taken by pregnant or breastfeeding women. Your doctor should discuss with you the possible effects of TOPALEX on the unborn child. Make sure you are very clear about the risks and benefits of using TOPALEX for epilepsy during pregnancy.

If you take TOPALEX during pregnancy, your baby has higher risk of birth defects, particularly cleft lip (split in the top lip) and cleft palate (split in the roof of the mouth). Newborn boys may also have a malformation of the penis (hypospadia).

These defects can develop early in pregnancy, even before you know you are pregnant.

If you take TOPALEX during pregnancy, your baby will be smaller than expected birth weight.

Talk to your doctor if you have questions about this risk during pregnancy. There may be other medicines to treat your condition that have lower risk of birth defects.

Tell your doctor immediately if you become pregnant while taking TOPALEX. You and your doctor should decide if you will continue to take TOPALEX while you are pregnant

Breastfeeding

The active substance in TOPALEX (topiramate) passes into breast milk. Effects have been seen in breastfed babies of treated mothers, including diarrhoea, feeling sleepy, feeling irritable, and poor weight gain. Therefore, your doctor will discuss with you whether you abstain from breastfeeding or whether to abstain from treatment with TOPALEX. Your doctor will take into account the importance of the medicine to the mother and the risk for the baby.

Mothers who breastfeed while taking TOPALEX must tell the doctor as soon as possible if the baby experiences anything unusual.

Driving and using machines

TOPALEX may cause you to be less alert than normal. Make sure you know how you are affected by this medicine before you drive, use machines or do anything else that could be dangerous if you are not alert.

Important information about some of the ingredients of TOPALEX:

TOPALEX tablets contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with rare hereditary conditions of lactose intolerance should not take TOPALEX tablets.

3. How to take TOPALEX

Do not share medicines prescribed for you with any other person.
Always take TOPALEX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
Your doctor will tell you how long your treatment with TOPALEX will last. Do not stop treatment early because you may experience a seizure (fit). If you have the impression that the effect of TOPALEX is too strong or too weak, tell your doctor or pharmacist.

Your doctor will start with a low dose and slowly increase the dose to the lowest amount needed to control your epilepsy.
Your doctor will start with a low dose and slowly increase the dose to the lowest amount needed to control your epilepsy.

It is recommended that the tablets not be broken. Always swallow the tablets with plenty of water.

If you are taking only TOPALEX to treat your epilepsy:

Your doctor will prescribe the correct dosage for you.

TOPALEX is taken twice a day. Take half the dose in the morning and half in the evening.

If you are taking TOPALEX and other anti-epileptic medicines:

Your doctor will prescribe the correct dosage for you.

TOPALEX is taken twice a day. Take half the dose in the morning and half in the evening.

If you use more TOPALEX than you should:

Signs and Symptoms

Overdosage of topiramate have been reported. Signs and symptoms included: convulsions (fits), drowsiness (feeling sleepy), difficulty speaking, blurred vision, double vision, impaired mental state, lethargy, problems with coordination, almost unconscious, low blood pressure, stomach pain, agitation, dizziness and depression.

Topiramate overdose can result in increased acid levels in the blood.

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

If you forget to take TOPALEX:

If you miss a dose, take it as soon as you remember. But, if it is almost time for the next dose, do not take the missed dose and then carry on as before.

Effects when treatment with TOPALEX is stopped:

Do not suddenly stop taking TOPALEX without first checking with your doctor.

TOPALEX should be withdrawn gradually.

Always check that you have enough tablets and do not run out.

4. POSSIBLE SIDE EFFECTS

TOPALEX can cause side-effects:

Frequent side effects include:

- Weight loss
- Tingling in the arms and legs
- Drowsiness or sleepiness
- Dizziness
- Diarrhoea
- Nausea
- Stuffy, runny nose and sore throat
- Tiredness
- Depression
- Changes in mood or behaviour, including anger, nervousness, sadness
- Weight gain
- Decrease or loss of appetite
- Reduced number of red blood cells
- Changes in thinking and alertness, including confusion, problems with concentration, memory or slowness in thinking
- Slurred speech
- Clumsiness, or problems with walking
- Involuntary shaking in the arms, hands or legs

- Reduced sense of touch or sensation
- Involuntary movement of the eyes
- Distorted sense of taste
- Visual disturbance, blurred vision, double vision
- Ringing sound in the ears
- Ear pain
- Shortness of breath
- Nose bleeds
- Vomiting
- Constipation
- Stomach pain
- Indigestion
- Dry mouth
- Tingling or numbness of the mouth
- Kidney stones
- Frequent urination
- Painful urination
- Hair loss
- Skin rash and/or itchy skin
- Joint pain
- Muscle spasms, muscle twitching or muscle weakness
- Chest pain
- Fever
- Loss of strength
- General feeling of feeling unwell
- Allergic reaction
- Cough

Less Frequent side-effects include:

- Crystals in the urine
- Abnormal blood counts, including reduced white blood cell count or platelet count, or increased eosinophils
- Irregular heartbeat or slowness of the heartbeat
- Swollen glands in the neck armpit or groin
- Increase in seizures
- Problems with verbal communication
- Drooling, increased saliva flow
- Restlessness or increased mental and physical activity
- Loss of consciousness
- Fainting
- Slow or diminished movements
- Disturbed or poor-quality sleep
- Impaired or distorted sense of smell
- Problems with handwriting
- Feeling of movement under the skin
- Eye problems including dry eyes, light sensitivity, involuntary twitching, tearing
- and decreased vision
- Decreased or loss of hearing
- Hoarseness of the voice
- Inflammation of the pancreas
- Gas
- Heartburn
- Loss of sensitivity to touch in the mouth
- Bleeding gums

- Fullness or bloating of the stomach, pressure on an area of the stomach causes pain
- Painful or burning sensations in the mouth
- Breath odour
- Leakage of urine and/or stools
- Urgent desire to urinate
- Pain in the kidney area and/or bladder caused by kidney stones
- Decrease or loss of sweating
- Skin discolouration
- Localised swelling in the skin
- Swelling of the face
- Swelling of the joints
- Musculoskeletal stiffness
- Increased acid levels in the blood
- Low potassium levels in the blood
- Increased appetite
- Increased thirst and drinking abnormally large amounts of fluid
- Low blood pressure or decrease in blood pressure that occurs when you stand up
- Hot flushing
- Flu like illness
- Cold extremities (e.g. hands and face)
- Problems with learning
- Disturbances in sexual function (erectile dysfunction, loss of libido)
- Hallucinations
- Decreased verbal communication
- Excessive skin sensitivity
- Impaired sense of smell
- Glaucoma which is a blockage of fluid in the eye causing increased pressure

in the eye, pain and decreased vision

- 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 (hyperammonemia), which can lead to a change in brain function (hyperammonemic encephalopathy).
- Renal tubular acidosis
- Stevens-Johnson syndrome - this causes a severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals. It is potentially life threatening
- Toxic epidermal necrosis - this causes blisters and peeling skin over much of the body. It is life threatening and more severe than Stevens Johnson syndrome (see above).
- Odour
- Swelling in the tissues around the eye
- Raynaud's syndrome. A disorder affecting the blood vessels, in the fingers, toes, ears and causing pain and cold sensitivity

<u>Side-effects of unknown frequency</u>:

- Maculopathy is a disease of the macula, the small spot in the retina where vision
- is keenest. You should call your doctor if you notice a change or decrease in your vision
- Swelling of the conjunctiva of the eye

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

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 TOPALEX tablets.

5. How to store TOPALEX

Store at or below 25° C. Keep container tightly closed.

Store in the original package/container.

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.

. **Do not use these tablets:**

- after the expiry date shown on the label.
- if the tablets do not look as described below

6. Contents of the pack and other information

What TOPALEX contains

The active ingredient in TOPALEX is topiramate

Other ingredients in the tablets include: carnauba wax ,

lactose, magnesium stearate , microcrystalline cellulose,

pregelatinised starch, sodium starch glycolate and

OPADRY white, yellow, pink.

What TOPALEX looks like and contents of the pack

TOPALEX are available in white plastic containers of 60 tablets.

TOPALEX tablets are available as embossed, coated tablets in the following strengths and colours:

25 mg : round white tablets, engraved with "TOP" on one side and "25" on the other.

50 mg : round light yellow tablets, engraved with “TOP" on one side and "50" on the other.

100 mg : round yellow tablets, engraved with “TOP" on one side and "100" on the other.

HOLDER OF CERTIFICATE OF REGISTRATION

JANSSEN PHARMACEUTICA (PTY) LTD

(Reg. No. 1980/011122/07)

2 Medical Street, Halfway House,

Midrand 1685, South Africa

www.janssen.com

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TOPALEX TABLETS: 04 December 2009

Most recently revised Patient Information Leaflet as approved by Council:

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