

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S 3

TOPLEP 25 Tablets

TOPLEP 50 Tablets

TOPLEP 100 Tablets

TOPLEP 200 Tablets

Topiramate

Contains Sugar: lactose

Each 25 mg tablet contains 5 mg lactose monohydrate

Each 50 mg tablet contains 10 mg lactose monohydrate

Each 100 mg tablet contains 20 mg lactose monohydrate

Each 200 mg tablet contains 40 mg lactose monohydrate

Read all of this leaflet carefully before you start taking TOPLEP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist, nurse or other health care provider.

TOPLEP 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 TOPLEP is and what it is used for
2. What you need to know before you take TOPLEP

3. How to use TOPLEP
4. Possible side effects
5. How to store TOPLEP
6. Contents of the pack and other information

1.What TOPLEP is and what it is used for

TOPLEP tablets contains topiramate

TOPLEP is indicated as monotherapy in patients with newly diagnosed epilepsy or for conversion to monotherapy in patients with epilepsy.

TOPLEP tablets are indicated as adjunctive therapy for adults and children over 4 years old who are inadequately controlled on conventional first line antiepileptic medicines for:

- partial onset seizures with or without secondarily generalised seizures.
- seizures associated with Lennox-Gastaut syndrome.
- primary generalized tonic clonic seizures

2.What you need to know before you take TOPLEP

Do not take TOPLEP :

- if you are hypersensitive (allergic) to topiramate or any of the other ingredients of TOPLEP

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

- if your child is below 2 years of age,
- if you are a woman who is pregnant, planning to become pregnant or breastfeeding

Do not take TOPLEP if any of the above applies to you.

If you are not sure, talk to your doctor or pharmacist before receiving TOPLEP. Do this even if they have applied in the past

Warnings and precautions

Take special care with TOPLEP :

- if you have kidney(s) or liver problems,
- if you have or have earlier had kidney stones. To avoid the risk of development of kidney stones, it is important to receive adequate amount of fluids, especially before or during exercise or when exposed to hot temperatures,
- if you have family history of renal stones,
- If you have eye problems, especially glaucoma. Symptoms may include sudden decrease in vision with or without eye pain and redness. If eye problems occur at any time during treatment with TOPLEP, discontinue it as rapidly as possible and contact your doctor,
- If you have a growth problem,
- If you are on a high fat diet (ketogenic diet),
- have a history of blood and body fluid abnormality (metabolic acidosis).

TOPLEP may increase the level of acid in your or your child's blood and body fluid (metabolic acidosis).

Symptoms of metabolic acidosis may include rapid and deep breathing associated with non-specific symptoms such as nausea, vomiting and stomach pain, feeling very weak or tired, weakness in arms and legs. This condition may increase if there is associated kidney disease, severe chest or lung problems, prolonged or repeated fits or seizures without any recovery between attacks (status epilepticus), diarrhoea, surgery or are on a high fat diet (ketogenic diet) or with certain medicines. If left untreated, metabolic acidosis can cause kidney stones, increased risk of fractures or growth problem in your child. If this condition develops or persists, your doctor may

want to reduce the dose or discontinue treatment with TOPLEP and may ask for blood tests at any time during treatment.

Tell your doctor or pharmacist while on treatment with TOPLEP :

- If you have an increase in frequency of fits.
- if you have thoughts about suicide or dying and unusual changes in behaviour. Pay attention to any changes, especially sudden changes in behaviour, thoughts, or feelings.
- If you have unusual changes in mood and depression.
- If you have impaired mental activities or alertness, tiredness, vomiting. These symptoms may be due to high ammonia levels in your blood causing disease of the brain called encephalopathy. This may happen when TOPLEP is taken alone or with a medicine called valproic acid.
- If you have decreased sweating and rise in body temperatures. People, especially children, should be watched for signs of decreased sweating and fever, especially in hot temperatures
- If you have weight loss. Weight should be checked regularly when using TOPLEP. If you or your child are losing too much weight while using TOPLEP, it should be supplemented with diet, or food intake should be increased.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Other medicines and TOPLEP:

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

Care is needed if you are taking:

- phenytoin, carbamazepine, valproic acid, phenobarbitone
- primidone (used to treat fits)
- digoxin (used for certain heart conditions)

- hormonal contraceptive pills (oral pills)
- water tablets (e.g. hydrochlorothiazide)
- metformin, glyburide, pioglitazone (used to treat high blood sugar)
- amitriptyline, imipramine, moclobemide, St John's Wort (used to treat depression)
- diazepam (used to treat anxiety, inability to sleep, muscle spasm)
- lithium (used to treat mania)
- proguanil (used to treat malaria)
- omeprazole (used to treat stomach ulcer and acid reflux)
- other medicines that can cause kidney stone formation (e.g. water tablets such as furosemide, bumetanide, acetazolamide; antibiotics such as sulphonamides, ciprofloxacin; anti-HIV medicine such as indinavir; antacids containing magnesium trisilicate).

TOPLEP with food and drink:

TOPLEP can be taken with or without meals

Pregnancy and Breastfeeding:

Do not take Toplep if you are pregnant, planning to become pregnant or breastfeeding. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking Toplep.

Driving and using machinery:

TOPLEP may cause drowsiness or dizziness. Do not drive or use machines, because TOPLEP could interfere with your ability to drive and use machines. Make sure you know how you react to TOPLEP before you drive, use machines, or engage in any

other activity that could be dangerous if you are not alert

Lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per the maximum recommended dose, that is to say essentially 'sodium-free'

3.How to take TOPLEP

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

Always take TOPLEP exactly as your doctor has instructed you. It is important to finish a full course of treatment.

You should check with your doctor or pharmacist if you are not sure.

Your doctor will usually start with a low dose of TOPLEP and slowly increase the dose until the best dose is found for you.

Adults:

TOPLEP when used in combination with other anti-epileptic medicines:

The usual starting dose is one TOPLEP 25 mg or 50 mg tablet taken once daily at bedtime for 1 week. Then your doctor could further increase your daily doses depending on your response to treatment up to 200 mg.

The tablets may be taken once daily or twice daily. Usually daily doses of 200 to 400 mg would be enough to control your epilepsy.

Toplep when used as single therapy:

The usual starting dose is one TOPLEP 25 mg tablet taken once daily at bedtime for 1 week. Then your doctor may further increase your daily doses depending on your response to treatment. Usually, daily doses of 100 mg would be enough. The recommended daily dose should not exceed 500 mg. However if required, your doctor may increase your daily doses up to 1000 mg.

Your dose may be different in case you have problems with your kidney(s) or you are on haemodialysis.

Children: The recommended daily doses for children would depend on the child's weight.

You should not give TOPLEP to your child if he is younger than 2 years of age.

Your doctor will tell you how long your treatment will last.

Always swallow the tablet(s) whole with plenty of water. It is important to drink plenty of water when taking TOPLEP tablets especially if you exercise or the weather is hot.

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

If you take more TOPLEP than you should:

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Remember to take this leaflet and/or the package with you to show the doctor what you have taken.

If you forget to take TOPLEP:

Take them as soon as you remember. However if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses. You should contact your doctor on how to proceed.

Effects when treatment with TOPLEP is stopped:

Take your tablets as directed and for as long as directed. Do not suddenly stop taking this medicine without first checking with your doctor.

If you have any further questions on the use of TOPLEP ask your doctor or pharmacist.

4.Possible side effects

TOPLEP can have side effects.

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

Stop taking TOPLEP and see a doctor, or go to a casualty department at your nearest hospital:

- If you get swelling of the hands, feet, ankles, face, lips or throat, which may cause difficult in swallowing or breathing. You could also notice an itchy, nettle rash (urticaria).
- 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,
- toxic epidermal necrosis, a life threatening condition related to, yet more severe than, Stevens-Johnson syndrome characterised by widespread blistering and sloughing of the outer layers of the skin

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TOPLEP. 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:

- slow or irregular heartbeat, feeling your heart beating in your chest,
- low blood pressure, low blood pressure upon standing (consequently some people taking TOPLEP may feel faint, dizzy or may pass out when they stand up or sit up suddenly),
- Stevens - Johnson syndrome, a potentially life-threatening condition that may present with sores in multiple mucosal sites (such as mouth, nose and eyes), a skin rash and blistering.

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:

- stuffy, runny nose or sore throat,
- tingling, pain and/or numbness of various body parts,
- sleepiness, tiredness,
- dizziness,
- nausea, diarrhoea,
- weight loss,
- anaemia (low blood count),
- loss of appetite, decreased appetite,
- aggression, agitation, anger, abnormal behaviour,
- difficulty falling or staying asleep,
- problems with speech or speech disorder, slurred speech,

- clumsiness or lack of coordination, feeling of unsteadiness when walking,
- decreased ability to complete routine tasks
- decreased, loss of or no sense of taste,
- involuntary trembling or shaking; rapid, uncontrollable movement of eyes,
- visual disturbance, such as double vision, blurred vision, decreased vision, difficulty focusing,
- sensation of spinning (vertigo) ringing in the ears, ear pain,
- shortness of breath,
- cough,
- nose bleeds,
- fever, not feeling well, weakness,
- vomiting, constipation, abdominal pain and discomfort, indigestion, stomach or intestinal infection,
- dry mouth,
- hair loss,
- itching,
- joint pain or swelling, muscle spasm, twitching, muscle aches or weakness, chest pain,
- weight gain.

Less Frequent side effects:

- decrease in platelets, decrease in white blood cells that help to protect you against infection, decrease in potassium level in the blood,
- increase in liver enzymes, increase in eosinophils (a type of white blood cell) in the blood,
- swollen glands in the neck, armpit or groin,
- increased appetite,

- elevated mood,
- hearing, seeing or feeling things that are not there, severe mental disorder,
- showing and/or feeling no emotion, unusual suspiciousness, panic attack,
- depressed mood with thoughts of committing suicide,
- problems with reading, speech disorder, problems and handwriting,
- restlessness, hyperactivity,
- slowed thinking, decreased wakefulness or alertness,
- reduced or slow body movements, involuntary abnormal or repetitive muscle movements,
- fainting,
- fits,
- abnormal sense of touch,
- impaired, distorted or no sense of smell,
- unusual feeling or sensation that may precede a migraine or a certain type of seizure,
- dry eye, sensitivity of the eyes to light, eyelid twitching, watery eyes,
- decreased or loss of hearing, loss of hearing in one ear,
- flushing, feeling warm,
- pancreatitis (inflammation of the pancreas),
- excessive passing of gas or wind, heartburn, abdominal fullness or bloating),
- bleeding gums, increased saliva, drooling, breath odour,
- vaginal bleeding,
- excessive intake of fluids, thirst,
- skin discolouration,
- muscle stiffness, pain in side,
- blood clot usually in a leg which causes pain and swelling,
- blood urine, incontinence (lack of control) of urine, urgent desire to urinate, flank or

- kidney pain,
- difficulty getting or keeping an erection, sexual dysfunction,
 - flu-like symptoms,
 - cold fingers and toes,
 - feeling drunk,
 - learning disability,
 - abnormally elevated mood,
 - loss of consciousness,
 - blindness in one eye, temporary blindness, night blindness,
 - lazy eye,
 - swelling in and around eyes,
 - numbness, tingling and colour change (white, blue then red) in fingers and toes when exposed to the cold,
 - inflammation of the liver, liver failure,
 - abnormal skin odour,
 - discomfort in your arms or legs,
 - kidney disorder.

If you notice any side effects not mentioned in the 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 TOPLEP

5. How to store TOPLEP

- Store at or below 25 °C, in the original package, protected from moisture.
- Do not store in bathrooms in order to protect from moisture.
- Keep all medicine out of the reach and sight of children.
- Do not take medicine after the expiry date stated on the container.

Return any 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 TOPLEP contains

The active substance is Topiramate

TOPLEP 25

Each tablet contains topiramate 25 mg.

TOPLEP 50

Each tablet contains topiramate 50 mg.

TOPLEP 100

Each tablet contains topiramate 100 mg.

TOPLEP 200

Each tablet contains topiramate 200 mg

The other ingredients are:

Lactose monohydrate (Pharmatose 200, microcrystalline cellulose (Avicel PH 101), pregelatinised starch (Starch 1500), sodium starch glycollate (Type A)

Coating material

Opadry 12B58956 White(25mg)

Hypromellose 5 cp (HPMC 2910), , macrogol PEG 400, polysorbate 80, titanium dioxide (CI No.77891),

Opadry 12B52749 Yellow (50 and 100 mg)

Hypromellose 5 cp (HPMC 2910), iron oxide yellow (CI No.77492), macrogol PEG 400, polysorbate 80 titanium dioxide

Opadry 12B56662 Brown (200 mg)

Hypromellose 5 cp (HPMC 2910), iron oxide red (CI No.77491) , macrogol PEG 400, polysorbate 80, titanium dioxide (CI No.77891)

What TOPLEP looks like and contents of the pack

TOPLEP 25

White, film coated, circular tablets debossed with 'TP1' on one side and plain on the other side.

TOPLEP 50

Yellow coloured, film coated, circular tablets debossed with 'TP2' on one side and plain on the other side.

TOPLEP 100

Yellow coloured, film coated, circular tablets debossed with 'TP3' on one side and plain on the other side.

TOPLEP 200

Peach coloured, film coated, circular tablets debossed with 'TP4' on one side and plain on the other side

Cartons contain a white opaque HDPE bottle with a desiccant and absorbent cotton wool containing 60 tablets

Holder Of Certificate Of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

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1724

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