PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]PRO-TOPIRAMATE
Topiramate tablets

Read this carefully before you start taking **PRO-TOPIRAMATE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PRO-TOPIRAMATE**.

What is PRO-TOPIRAMATE used for?
PRO-TOPIRAMATE is used:
- to control epilepsy (seizures) in adults and children (6 years of age and older).
- with other antiepileptic drugs to manage epilepsy in adults and children (2 years of age or older).
- To prevent migraine headaches in adults (18 years and older).

How does PRO-TOPIRAMATE work?
PRO-TOPIRAMATE is an antiepileptic drug used to treat epilepsy. It affects chemicals in the brain that are involved in sending signals to the nerves. This reduces the chances of having seizures and migraines.

What are the ingredients in PRO-TOPIRAMATE?
Medicinal ingredient: Topiramate
Non-medicinal ingredients: Colloidal Silicon Dioxide, Copovidone, Lactose Monohydrate, Magnesium Stearate, Sodium Starch Glycolate. In addition, the coating of the tablet contains:
25 mg: Hydroxypropyl Methylcellulose, Polydextrose, Polyethylene Glycol, Titanium Dioxide and Triethyl Citrate.
100 mg: Iron Oxide Yellow, Polyethylene Glycol, Polyvinyl Alcohol, Talc, and Titanium Dioxide.
200 mg: Iron Oxide Red, Polyethylene Glycol, Polyvinyl Alcohol, Talc, Titanium Dioxide.

PRO-TOPIRAMATE comes in the following dosage forms:
Tablets: 25 mg, 100 mg, 200 mg

Do not use PRO-TOPIRAMATE if:
- you/your child are allergic to topiramate, or any of the ingredients in PRO-TOPIRAMATE.
- you require treatment for migraine headaches and are pregnant or a woman of childbearing potential and are not using a highly effective method of birth control.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRO-TOPIRAMATE. Talk about any health conditions or problems you may have, including if you/your child:

- have or have had kidney stones.
- have or have had metabolism or kidney problems.
- have or have had liver problems.
- have conditions that may increase the risk of developing metabolic acidosis (high levels of acid in the blood) such as:
  - renal disease,
  - severe respiratory disorders,
  - status epilepticus (seizure lasting more than 5 minutes, or more than one seizure within 5 minutes),
  - diarrhea,
  - surgery, and
  - ketogenic diet (low carbohydrate and high fat diet).
- have a family history of hypercalciuria (high levels of calcium in the urine).
- engage in activities where loss of consciousness could result in serious danger to themselves or those around them (including swimming, driving a car, climbing in high places, etc.).
- **are breastfeeding (nursing) or plan to breastfeed. PRO-TOPIRAMATE can pass into breast milk and can harm your baby.**
- **are pregnant or plan to become pregnant. PRO-TOPIRAMATE for migraine prevention is contraindicated in pregnant women.**
- have a growth problem.

Other warnings you should know about:

PRO-TOPIRAMATE can cause serious effects, including:

- **Hyperammonemia:**
  Treatment with PRO-TOPIRAMATE can cause hyperammonemia (high levels of ammonia in the blood) that can affect the brain. Tell your healthcare professional if you notice or develop any unexplained lethargy (lack of energy), vomiting, changes in mental status, or hypothermia (low body temperature). Your healthcare professional may monitor your health and the ammonia levels of your blood. This will help them decide to discontinue your treatment with PRO-TOPIRAMATE.

- **Oligohidrosis and hyperthermia:**
  Treatment with PRO-TOPIRAMATE can cause oligohidrosis (decreased or absence of sweating) and hyperthermia (high body temperature), especially in children. Your healthcare professional will monitor you/your child closely for symptoms of decreased sweating and increased body temperature. However, if you/your child notices or develops any of these symptoms, tell your healthcare professional immediately. You/your child should be adequately hydrated before and during activities such as exercise or exposure to warm temperatures. Tell your healthcare professional if you/your child are taking drugs that

increase the risk of developing heat-related disorders (e.g., carbonic anhydrase inhibitors and drugs with anticholinergic activity).

- **Metabolic acidosis:**
  Treatment with PRO-TOPIRAMATE can cause metabolic acidosis (high levels of acid in the blood) in both adults and children. This can lead to brittle or soft bones (osteoporosis, osteomalacia, or osteopenia), rapid breathing, persistent lack of energy, loss of appetite, heart problems, confused thinking or reduced consciousness. If you/your child develops or notices any of these symptoms, tell your healthcare professional immediately. Your healthcare professional may perform a blood test to measure the level of acid in your/your child's blood before and regularly during your treatment with PRO-TOPIRAMATE.

- **Mental and motor impairment:**
  Treatment with PRO-TOPIRAMATE can affect your mental and motor performance. These can cause psychomotor slowing, difficulty with concentration, speech problems, word-finding difficulties, drowsiness, fatigue, and mood disturbances.

- **Eye problems:**
  Treatment with PRO-TOPIRAMATE can cause eye problems that can lead to vision loss. If you/your child notices any changes to vision or eye pain, tell your healthcare professional immediately and seek medical help. Your doctor may discontinue treatment with PRO-TOPIRAMATE.

- **Kidney stones:**
  Treatment with PRO-TOPIRAMATE has been associated with the formation of kidney stones, especially those with an increased risk of developing kidney stones. Your healthcare professional will recommend you/your child to drink lots of fluids when taking PRO-TOPIRAMATE to decrease your chances of getting kidney stones.

- **Serious skin reactions:**
  Treatment with PRO-TOPIRAMATE and allergic reactions can cause serious skin reactions including Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN). This can lead to symptoms such as rashes, sore throats, fevers, and mouth ulcers. If you/your child notices any signs of serious skin reactions (even mild symptoms), tell your healthcare professional immediately. Your doctor may discontinue treatment with PRO-TOPIRAMATE.

- **Suicidal thoughts or behaviour:**
  Antiepileptic drugs such as PRO-TOPIRAMATE may increase the risk of suicidal thoughts and behaviours (harming or killing themselves). If at any time you have these thoughts, immediately contact your healthcare professional.

- **Weight loss:**
  Treatment with PRO-TOPIRAMATE can lead to weight loss. Your healthcare professional may instruct you/your child to take a dietary supplement or increase your food intake.

See the **Serious side effects and what to do about them** table, below, for more information on these and other serious side effects.

Driving and using machines: PRO-TOPIRAMATE can cause drowsiness, dizziness, visual disturbances, blurred visions, and other related symptoms. Before you drive or do tasks that require special attention, wait until you know how you respond to PRO-TOPIRAMATE.

Laboratory tests and monitoring: Your healthcare professional may monitor and assess your health by performing blood tests. These tests can be performed before and during your treatment with PRO-TOPIRAMATE to measure your bicarbonate and ammonia.

Pregnancy and breastfeeding:
PRO-TOPIRAMATE may reduce the efficacy of contraceptives. If you are taking oral contraceptives, tell your doctor about any changes in your bleeding patterns (breakthrough bleeding/spotting). In addition, your doctor may ask you to take a pregnancy test before you start taking PRO-TOPIRAMATE.

EPILEPSY ONLY

- If you take PRO-TOPIRAMATE during pregnancy:
  - your baby has a higher risk for birth defects called cleft lip, cleft palate, and other malformations (e.g., anomalies involving various body systems including limbs and heart). These defects can begin early in pregnancy, even before you know you are pregnant. Cleft lip and cleft palate may happen even in children born to women who are not taking any medicines and do not have other risk factors.
  - your child is at risk for developing autism and other intellectual disabilities.
- Talk to your healthcare professional as there may be other medicines to treat your condition that have a lower chance of birth defects.
- If you are pregnant, able to get pregnant or think you are pregnant and are being treated for epilepsy, you should talk to your healthcare professional about using other possible treatments instead of PRO-TOPIRAMATE. If the decision is made to use PRO-TOPIRAMATE, you should use a highly effective birth control (contraception) during your treatment. You should talk to your doctor about the best kind of birth control to use while you are taking PRO-TOPIRAMATE.
- Treatment with topiramate during pregnancy can cause metabolic acidosis that may have harmful effects on your baby. Talk to your healthcare professional if PRO-TOPIRAMATE has caused metabolic acidosis during your pregnancy.
- If you take PRO-TOPIRAMATE during pregnancy, you may have pre-term labour or your baby may be born early (premature delivery). Talk to your healthcare professional if you have questions about this risk during pregnancy.

- If you become pregnant while taking PRO-TOPIRAMATE®, tell your doctor right away. You and your doctor should decide if you will continue to take PRO-TOPIRAMATE while you are pregnant.

  Pregnancy Registry: If you become pregnant while taking PRO-TOPIRAMATE, talk to your doctor about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic medicine during pregnancy. Information on the registry can also be found at the following website http://www.aedpregnancyregistry.org/.

MIGRAINE PREVENTION ONLY

- PRO-TOPIRAMATE is NOT to be used to prevent migraine headaches in pregnant women or women of childbearing potential who are not using a highly effective method of birth control.

Do not stop PRO-TOPIRAMATE without first talking to your healthcare professional. Stopping PRO-TOPIRAMATE suddenly can cause serious problems including seizures.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.
The following may interact with PRO-TOPIRAMATE:

- medicines used to treat heart failure such as digoxin;
- central nervous system (CNS) depressants such as alcohol;
- medicines containing hormones used for birth control (hormonal contraceptives) including pills, implants, patches, or injections;
- medicines used to treat diabetes such as metformin, glyburide, or pioglitazone;
- medicines used to treat bipolar disorder such as lithium or risperidone;
- medicines used to treat depression such as amitriptyline;
- medicines used to treat high blood pressure such as diltiazem or hydrochlorothiazide;
- medicines such as blood thinners (anticoagulants);
- medicines that increase the risk of developing kidney stones such as acetazolamide;
- medicines used to treat epilepsy (seizures) such as phenytoin, valproic acid (valproate), or carbamazepine.

How to take PRO-TOPIRAMATE:

- PRO-TOPIRAMATE is usually taken twice a day (in the morning and in the evening). However, your doctor may tell you to take it once a day depending on your situation.
- PRO-TOPIRAMATE can be taken with or without food.
- PRO-TOPIRAMATE should be swallowed whole with plenty of water. Do not break or crush your tablets.
- Always check that you have enough PRO-TOPIRAMATE tablets and do not run out.

- Do not stop taking PRO-TOPIRAMATE or adjust the amount of PRO-TOPIRAMATE you/your child is/are taking without first checking with your doctor.

Usual dose:
Your doctor will determine the right dose for you/your child. Take PRO-TOPIRAMATE exactly as prescribed by your doctor. Your doctor may start with a low dose and slowly adjust your dose as needed.

EPILEPSY ONLY

PRO-TOPIRAMATE taken alone:

- **Adults and children (6 years of age or older):** The starting dose is 25 mg in the evening. The usual maintenance dose is 100 mg to 400 mg per day in two divided doses.

PRO-TOPIRAMATE taken with other antiepileptic drugs:

- **Adults (17 years of age or older):** The starting dose is 50 mg in the evening. The usual maintenance dose is 200 mg to 400 mg per day in two divided doses.
- **Children (2 to 16 years of age):** The starting dose is 25 mg in the evening (or less, depending on weight). The healthcare professional will determine the appropriate maintenance dose based on weight.

MIGRAINE PREVENTION ONLY

- **Adults (18 years of age or older):** The starting dose is 25 mg in the evening. The usual maintenance dose is 100 mg per day in two divided doses.

Remember: This medicine has been prescribed for you/your child. Do not give it to anybody else.

Overdose:

If you think you, or a person you are caring for, have taken too much PRO-TOPIRAMATE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:
If you/your child miss/misses 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. Instead, take the next scheduled dose. Do not try to make up for the missed dose by taking a double dose next time.

What are possible side effects from using PRO-TOPIRAMATE?
These are not all the possible side effects you may have when taking PRO-TOPIRAMATE. If you experience any side effects not listed here, tell your healthcare professional.

Side effects in adults include: co-ordination problems, slow thinking, and forgetfulness, dizziness, tiredness, tingling, headache, upper respiratory tract infection (e.g., colds, bronchitis), drowsiness, agitation, decrease in appetite, speech disorders (e.g., hesitancy or word-finding difficulty), depression, emotional lability, mood swings, nausea, taste changes, and weight loss.

Side effects in children include: forgetfulness, tiredness, drowsiness, nervousness, decrease in appetite, weight loss, upper respiratory tract infection (e.g., colds, bronchitis), headache, tingling and aggressive behaviour.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
RARE			
Decreased sweating and increased body temperature (fever)			✓
Eye disorders: sudden, severe eye pain, loss of part or all of vision, blurred, distorted, double or worsening vision, increased pressure in the eyes, halos around lights, eye pain or redness, dilated pupils increased sensitivity of the eyes to light, swelling and itching of the eyelids, eye irritation, blocked eye veins, nausea, vomiting, severe headache			✓
Hyperammonemia (high ammonia levels in the blood): decreased alertness, tiredness or fatigue, vomiting, low body temperature < 35°C, confusion, irritability, or refusal to eat meat or high protein products		✓	
Kidney stones: blood in the urine, or pain in the lower back or genital area		✓	
VERY RARE			
Allergic reaction including serious skin reaction (e.g. Stevens-Johnson syndrome [SJS]): red skin, hives, skin rashes, or itching; swelling of the lips, face, tongue, throat or parts of the body; difficulty swallowing or breathing; wheezing or shortness of breath; fever; mouth ulcers; redness, blistering and/or peeling skin (particularly around the lips, mouth, eyes, nose or genitals and accompanied by fever, chills, headache, cough, body aches or swollen glands); sore mouth or eyes; drop in blood pressure; feeling sick to your stomach and throwing up			✓

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
Confusion, problems with concentration, attention, memory, and/or speech		✓	
Metabolic Acidosis (high acid levels in the blood): unexplained tiredness, loss of appetite, irregular heartbeat, impaired consciousness, rapid breathing, or confusion		✓	
Suicidal thoughts or actions (hurting or killing yourself)		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or

- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Do not use this product after the expiry date written on the package.
- Store between 15°C – 30°C in a dry place in the original package. Protect from moisture.
- Keep out of reach and sight of children.

If you want more information about PRO-TOPIRAMATE:

- Talk to your healthcare professional.

Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html), or by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or medinfo@prodoc.qc.ca

This leaflet was prepared by Pro Doc Ltée.

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