PART III: CONSUMER INFORMATION

[Pr]PRO-TOPIRAMATE

Topiramate Tablets, House Standard

This leaflet is Part III of a three-part "Product Monograph" published when PRO-TOPIRAMATE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PRO-TOPIRAMATE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- PRO-TOPIRAMATE has been prescribed to you/your child to control epilepsy.

- PRO-TOPIRAMATE may also be prescribed to you to prevent your migraine headaches if you are an adult patient (over 18 years of age) with 4 or more attacks per month and are not responding to acute treatment.

What it does:

PRO-TOPIRAMATE affects chemicals in the brain that are involved in sending signals to the nerves. PRO-TOPIRAMATE belongs to a group of medicines used to treat epilepsy.

When it should not be used:

- You/your child should not use PRO-TOPIRAMATE if you are allergic to any of the ingredients in the product. Contact your doctor immediately if you experience an allergic reaction (e.g., skin rash, hives) or any severe or unusual side effects.
- You should not use PRO-TOPIRAMATE to prevent your migraine headaches if you are pregnant or a woman of childbearing potential and are not using an effective method of birth control.
- For the prevention of other types of headaches that are different from migraine attacks.
- For the acute treatment of migraine headache.

What the medicinal ingredient is:

topiramate

What the non-medicinal ingredients are:

Colloidal Silicon Dioxide, Copovidone, Lactose, 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.

What dosage forms it comes in:

Tablets: 25 mg, 100 mg, 200 mg

WARNINGS AND PRECAUTIONS

BEFORE you use PRO-TOPIRAMATE talk to your doctor or pharmacist if:

- you drive a vehicle, use machines, perform hazardous tasks during your work or do anything else that could be dangerous if you are not alert.
- you/ your child have or have had kidney stones or kidney disease. Your doctor may want you to increase the amount of fluids you/your child drink(s) while taking this medicine.
- you/your child have or have had liver disease.
- you/your child have or have had depression, mood
- problems, or suicidal thoughts or behaviour.
- you/your child have a history of metabolic acidosis (too
- much acid in the blood).
- you/your child have weak, brittle, or soft bones (osteomalacia, osteoporosis, osteopenia, or decreased bone density).
- you/your child have eye problems, especially glaucoma.
- you/your child have diarrhea.
- you/your child are having surgery.
- you/your child have or have had any medical problems or allergies.
- **you are breast-feeding (nursing) PRO-TOPIRAMATE passes into breast milk and can harm your baby. You and your doctor should decide whether you should take PRO-TOPIRAMATE or breast-feed, but not both.**
- you/your child are/is taking medicines that slow down the nervous system (CNS depressants).
- **you/your child are taking oral contraceptives and PRO-TOPIRAMATE tablets; tell your doctor about any changes in your bleeding patterns (breakthrough bleeding/spotting).**
- **you are pregnant or plan to become pregnant.**
- you are taking a ketogenic diet (a diet high in fat and low in protein and sugar).
- you consume alcohol regularly.
- you/your child have a growth problem.

EPILEPSY ONLY

- **If you take PRO-TOPIRAMATE during pregnancy, your baby has a higher risk for birth defects called cleft lip and cleft palate. 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.**
- **There may be other medicines to treat your condition that have a lower chance of birth defects.**

- **All women of childbearing age who are being treated for epilepsy should talk to their healthcare providers about using other possible treatments instead of PRO-TOPIRAMATE. If the decision is made to use PRO-TOPIRAMATE, you should use effective birth control (contraception) unless you are planning to become pregnant. You should talk to your doctor about the best kind of birth control to use while you are taking PRO-TOPIRAMATE.**
- **Metabolic acidosis may have harmful effects on your baby. Talk to your healthcare provider if PRO-TOPIRAMATE has caused metabolic acidosis during your pregnancy.**
- **Tell your doctor right away if you become pregnant while taking PRO-TOPIRAMATE. 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 website http://www.massgeneral.org/aed/.

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

Other Precautions:
PRO-TOPIRAMATE may cause some people to be less alert than normal. Make sure you know how you/your child are/is affected by this medication before you drive, use machines, or do anything else that could be dangerous if you are not alert.

PRO-TOPIRAMATE may reduce the efficacy of oral contraceptives even in the absence of breakthrough bleeding. Therefore, oral contraceptives containing not less than 30 µg of estrogen should be used.

A very small number of people may have thoughts of suicide.

PRO-TOPIRAMATE can increase the level of acid in your blood (metabolic acidosis). If left untreated, metabolic acidosis can cause brittle or soft bones (osteoporosis, osteomalacia, osteopenia), kidney stones, can slow the rate of growth in children, and can harm your baby if you are pregnant. Metabolic acidosis can happen with or without symptoms.

Your doctor should do a blood test to measure the level of acid in your blood before and periodically during your treatment with PRO-TOPIRAMATE.

Rarely, blood tests have shown a slight increase in acidity. In many cases, there are no symptoms from this increased acidity but some people may experience symptoms such as rapid breathing, persistent lack of energy and loss of appetite. Some people may experience more serious symptoms such as heart problems, confused thinking or reduced consciousness.

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

INTERACTIONS WITH THIS MEDICATION

Tell your doctor about all medications (prescription and non-prescription) and dietary supplements you/your child are/is using. It is especially important that your doctor know if you/your child are/is taking digoxin, oral contraceptives, glyburide, lithium, risperidone, diltiazem, or any other antiepileptic drugs, such as phenytoin, valproic acid or carbamazepine.

PROPER USE OF THIS MEDICATION

PRO-TOPIRAMATE is usually taken twice a day; however, your doctor may tell you to take it once a day or at a higher or lower dose.

Never stop taking, increase or decrease the amount of PRO-TOPIRAMATE you are taking unless your doctor tells you to.

Swallow the Tablets and take with plenty of water. You/your child can take the Tablets with or without food. Do not break or crush your tablets.

Always check that you have enough Tablets and do not run out. Do not suddenly stop taking this medicine without first checking with your doctor.

EPILEPSY
It is important that you take PRO-TOPIRAMATE exactly as your doctor has instructed. Your doctor will start with a low dose and slowly increase the dose to the lowest amount needed to control your/your child's epilepsy.

Usual dose:
PRO-TOPIRAMATE taken alone: The usual maintenance dose in adults and children (6 years of age and older) is between 100 mg/day and 400 mg/day. PRO-TOPIRAMATE is usually taken twice a day.

PRO-TOPIRAMATE taken in combination with other antiepileptic drugs: The usual adult maintenance dose is 200 mg to 400 mg /day.

In children, dosing is based on weight and the dose is approximately 5 to 9 mg/kg/day.

PRO-TOPIRAMATE is not indicated for use in patients under 2 years of age.

MIGRAINE PROPHYLAXIS
It is important that you follow your doctor's instructions carefully to help reduce the chances of getting a migraine headache. Your doctor will start treatment with a dose of 25 mg to be taken at night. Your doctor will then increase your dose to the lowest amount needed to prevent migraine headaches.

Usual dose:
The usual adult dose is 100 mg per day. PRO-TOPIRAMATE is taken twice a day (50 mg in the morning and 50 mg at night). Your doctor may tell you to use a lower or higher dose.

PRO-TOPIRAMATE is not indicated for the prevention of migraine attacks in patients under 18 years of age.

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

Overdose:

In case of a drug overdose, immediately go to the nearest emergency room even if you do not feel sick. Make sure you take your medicine bottle with you to show the doctor.

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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- Any medicine may have unwanted effects. Tell your doctor or pharmacist about any unusual sign or symptom whether listed or not.
- Contact your doctor immediately or go to the Emergency Room if you/your child experience/experiences sudden worsening of vision, blurred vision or painful/red eye(s).
- PRO-TOPIRAMATE 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 hospitalized for this condition. Make sure you/your child increase/ increases and maintain/maintains fluid intake prior to and during activities such as exercise and exposure to warm temperatures. Call your doctor right away if you/your child have/has a fever or decreased sweating.
- High ammonia in the blood can affect your mental activities, slow your alertness, make you feel tired, or cause vomiting.
- Taking PRO-TOPIRAMATE when you/your child are/is also taking valproic acid can cause a drop in body temperature to less than 35ºC (95ºF), a feeling of tiredness, confusion, or coma.
- Drink plenty of fluids when taking PRO-TOPIRAMATE to decrease your chances of getting kidney stones.
- Side effects reported most often in adults are: *co-ordination problems, difficulty concentrating, slow thinking, confusion and forgetfulness, dizziness, tiredness, tingling, headache, upper respiratory tract infection (e.g., colds, bronchitis) and drowsiness*. Less frequently reported side effects are: *agitation, decrease in appetite, speech disorders (e.g., hesitancy* or *word-finding difficulty*), *depression, emotional lability, vision disorders (e.g., double vision), mood swings, nausea, taste changes, weight loss and kidney stones (may include symptoms such as blood in the urine, or low back pain or pain in the genital area).*
- In children, the following side effects were associated with the use of topiramate: *difficulty concentrating, forgetfulness, tiredness, drowsiness, nervousness, decrease in appetite, weight loss, upper respiratory tract infection (e.g., colds, bronchitis), headache, fever, tingling and aggressive behaviour*.
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SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or pharmacist right away		Seek urgent medical attention
		Only if severe	In all cases	
Rare	*Kidney stones* (blood in the urine or pain in the lower back or genital area)		✓	
	Sudden worsening of vision, blurred vision with painful/red eye(s), loss of part of the field of vision			✓
	Decreased sweating and increased body temperature (fever)			✓
Very Rare	*Metabolic Acidosis* (unexplained tiredness, loss of appetite, irregular heartbeat, and impaired consciousness)		✓	
	Confusion, problems with concentration, attention, memory, and/or speech		✓	
	Thoughts of suicide or hurting yourself		✓	

	High blood *ammonia* (This happens when taken with a medicine called valproic acid.) (decreased alertness, tiredness or fatigue, vomiting)		✓	
	Allergic reaction (red skin, hives, itching, swelling of the lips, face, tongue, throat, trouble breathing, wheezing, shortness of breath, skin rashes, blisters of the skin, sore mouth or eyes)			✓

Uncommon side effects – between 1 and 10 reports in every 1000 patients exposed
Rare side effects – from 1 to less than 10 reports in every 10,000 patients exposed
Very rare side effects-–less than1 report in every 10,000 patients exposed

This is not a complete list of side effects. If you have any unexpected effects while taking this drug, contact your doctor or pharmacist.

HOW TO STORE IT

- Do not use this product after the expiry date written on the package.
- Store between 15-30°C in a dry place.
- Keep this and all medicines in a safe place out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at **www.healthcanada.gc.ca/medeffect .**

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals, can be obtained by contacting contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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