

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

^{Pr}APO-TOPIRAMATE Topiramate Tablets

This leaflet is Part III of a three-part “Product Monograph” published when APO-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 APO-TOPIRAMATE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

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

- APO-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:

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

When it should not be used:

You/your child should not use APO-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 APO-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.

APO-TOPIRAMATE should not be used for:

- the prevention of other types of headaches that are different from migraine attacks.
- the acute treatment of migraine headache.

What the medicinal ingredient is:

topiramate

What the important nonmedicinal ingredients are:

Tablets: methylcellulose, croscarmellose sodium, magnesium stearate, colloidal silicon dioxide, hydroxypropyl methylcellulose, hydroxypropyl cellulose, polyethylene glycol, titanium dioxide, purified water, yellow iron oxide (50 mg and 100 mg strengths) and red iron oxide (200 mg strength).

What dosage forms it comes in:

Tablets: 25 mg, 50 mg, 100 mg and 200 mg

WARNINGS AND PRECAUTIONS

BEFORE you use APO-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.
- any medical problems and any allergies you/your child have or have had in the past.
- **EPILEPSY ONLY**
you are pregnant, or if you are planning to become pregnant.

If you become pregnant while taking APO-TOPIRAMATE, talk to your healthcare provider about registering with the North American Antiepileptic Drug 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.aedpregnancyregistry.org/>.

APO-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.

- **you are breast-feeding (nursing).**
- you/your child are/is taking medicines that slow down the nervous system (CNS depressants).
- **you/your child are taking oral**

IMPORTANT: PLEASE READ

contraceptives and APO-TOPIRAMATE tablets, tell your doctor about any changes in your bleeding patterns (breakthrough bleeding/spotting).

- 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

Other Precautions:

APO-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.

APO-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.

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 discontinue this medication without talking to your doctor first.

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, valproate or carbamazepine.

PROPER USE OF THIS MEDICATION

APO-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 APO-TOPIRAMATE you are taking unless your doctor tells you to.

Swallow the tablets 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 APO-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 you/your child's epilepsy.

Usual dose:

APO-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. APO-TOPIRAMATE is usually taken twice a day.

APO-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.

MIGRAINE

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. APO-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.

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.

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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).
- Decreased sweating may occur while taking APO-TOPIRAMATE. 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. Contact your doctor if you/your child are/is not sweating as usual or show/shows signs of increased body temperature.
- Side effects reported most often in adults were: *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 were: *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.*

		Only if severe	In all cases	
Uncommon	Sudden worsening of vision, blurred vision with painful/red eye(s)			✓
	<i>Allergic reaction</i> (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)			✓
	Decreased sweating		✓	
	Thoughts of suicide or hurting yourself		✓	
Rare	<i>Kidney stones</i> (blood in the urine or pain in the lower back or genital area)		✓	
Very Rare	<i>Metabolic Acidosis</i> (unexplained tiredness, loss of appetite, irregular heartbeat, and impaired consciousness)		✓	
	Confusion, problems with concentration, attention, memory, and/or speech		✓	
	<i>High blood ammonia</i> (decreased alertness, tiredness or fatigue, vomiting)		✓	

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 than 1 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.

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

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 away from children.

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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 0701D
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

For more information, please contact your doctor, pharmacist or other healthcare professional. This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting DISpedia, Apotex's Drug Information Service, at 1-800-667-4708. This leaflet can also be found at <http://www.apotex.ca/products>.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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