

PART III: CONSUMER INFORMATION

**Pr APO-GABAPENTIN
(gabapentin)**

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

Please read this information carefully before you start to take your medicine, even if you have taken this drug before. Keep this information with your medicine in case you need to read it again. For further information or advice, please ask your doctor or pharmacist.

ABOUT THIS MEDICATION

What the medication is used for:

APO-GABAPENTIN (gabapentin) belongs to the family of medicines called antiepileptic drugs and is used for treating epilepsy (seizures).

What it does:

APO-GABAPENTIN has been prescribed for you by your doctor to reduce your number of seizures.

When it should not be used:

Do not use APO-GABAPENTIN if you are allergic to it or any of the components in the formulation (see list of components under nonmedicinal ingredients). Stop taking the drug and contact your doctor immediately if you experience an allergic reaction or any severe or unusual side effects while taking the drug.

What the medicinal ingredient is:

Gabapentin

What the nonmedicinal ingredients are:

APO-GABAPENTIN capsules contain the following non-medicinal ingredients: croscarmellose sodium, magnesium stearate, and talc. The hard gelatin capsule shells contain edible blue ink, gelatin, iron oxide red (400 mg capsules only), iron oxide yellow (300 and 400 mg capsules only), silicon dioxide, sodium lauryl sulfate, and titanium dioxide.

APO-GABAPENTIN tablets contain the following non-medicinal ingredients: copovidone, hydroxypropyl cellulose, hydroxypropyl methylcellulose, magnesium stearate, polyethylene glycol, and titanium dioxide.

What dosage forms it comes in:

APO-GABAPENTIN is available in both capsules (containing 100 mg, 300 mg or 400 mg gabapentin) and in tablets (containing 600 mg or 800 mg of gabapentin).

WARNINGS AND PRECAUTIONS

BEFORE you use APO-GABAPENTIN tell your doctor or pharmacist:

- Any health conditions or problems you may have, including kidney disease, breathing or lung problems.
- If you are taking any other medicines (prescription and non-prescription).
- If you have ever had an allergic reaction to medication, food, etc.
- If you are pregnant or thinking about becoming pregnant.
- If you are breast-feeding or plan to breastfeed your baby. Gabapentin passes into breast milk; however, it is not known if gabapentin can harm your baby. You and your doctor should decide whether you should take gabapentin or breastfeed, but not both.
- If you have a history of alcohol or drug abuse.
- Your habits of alcohol consumption.
- If you drive a vehicle or perform hazardous tasks during your work.
- A small number of people being treated with anti-epileptics have had thoughts of harming or killing themselves. If at any time you have these thoughts when taking APO-GABAPENTIN, contact your doctor immediately.

It is important for your doctor to have all of the above information before prescribing treatment and dosage.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor if you start or stop taking opioids such as morphine or hydrocodone. Opioids may increase the levels of APO-GABAPENTIN in your blood.

Tell your doctor immediately if you experience increased side effects such as drowsiness or slowed breathing while taking APO-GABAPENTIN with an opioid or other sedatives and tranquilizers. The dose of these drugs or APO-GABAPENTIN may need to be adjusted.

Avoid alcoholic drinks while taking APO-GABAPENTIN.

IMPORTANT: PLEASE READ

PROPER USE OF THIS MEDICATION

Usual dose:

- It is very important that you take APO-GABAPENTIN exactly as your doctor has instructed.
- APO-GABAPENTIN may be taken with or without food.
- You should not increase or decrease the amount of APO-GABAPENTIN you are taking unless your doctor tells you to.
- Do not stop taking it abruptly because your seizures may increase.

Overdose:

If you think you have taken too much APO-GABAPENTINE, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Signs of overdose may include: dizziness, drowsiness, unusually weak breathing, loss of consciousness.

Missed Dose:

If you miss a dose, take it as soon as possible. However, if it is within 4 hours of your next dose do not take the missed dose and return to your regular dosing schedule. Do not allow more than 12 hours to go by between doses because your seizures may increase. If that happens, consult your doctor as soon as possible.

REMINDER: This medicine has been prescribed only for you. Do not give it to anybody else, as they may experience undesirable effects, which may be serious.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

This is not a complete list of side effects. For any unexpected effects while taking APO-GABAPENTIN, contact your doctor or pharmacist.

Like all medications, APO-GABAPENTIN can cause some side effects. You may not experience any of them. For most patients these side effects are likely to be minor and temporary. However, some may be serious. Some of these side effects may be dose related. Consult your doctor if you experience these or other side effects, as the dose may need to be adjusted.

- Call your doctor immediately if your seizures get worse.

- When you first begin taking APO-GABAPENTIN you may experience some side effects such as agitation, drowsiness, dizziness, lack of muscle coordination, and fatigue. Consult your doctor if you experience any of these, as the dose may have to be adjusted.
- If your epilepsy is not controlled, it is very important not to perform any potentially hazardous tasks, such as driving a car or operating dangerous machines. If your epilepsy is controlled, it is important to refrain from potentially dangerous tasks until you are sure this medication does not affect your mental alertness or physical coordination.
- The following side effects have been reported when gabapentin is abruptly stopped: anxiety, sleeplessness, nausea, pain, and sweating.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM					
Symptom / effect	Talk with your doctor or pharmacist		Only if severe	In all cases	Seek Emergency Medical Attention
Common	Edema: Swelling of legs, ankles or feet.		✓		
Uncommon	Severe allergic reactions: fever, rash, swollen lymph nodes, hives, sore mouth, sore eyes or swelling of lips, throat or tongue, difficulty breathing				✓
	Respiratory Depression: slow, shallow or weak breathing.				✓
	Heart palpitations		✓		
	Chest pains		✓		
	Seizures		✓		
	Hallucinations				✓
	Unusual changes in mood		✓		
	Suicidal thoughts or		✓		

IMPORTANT: PLEASE READ

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Seek Emergency Medical Attention
	Only if severe	In all cases	
hurting yourself			
Jaundice: yellowing of skin; dark urine		✓	
Rhabdomyolysis: Unusual muscle movement or tone; unexplained muscle pain or tenderness or weakness, dark urine, nausea and/or vomiting		✓	
Incontinence: inability to control urination		✓	
		✓	
Unknown		✓	
Sleeplessness		✓	
Confusion		✓	
Loss of consciousness		✓	
Hyponatremia (low sodium in the blood): lethargy, confusion, muscular twitching or worsening of convulsions		✓	
Hypoglycemia or Hyperglycemia		✓	
Blood glucose fluctuations (for patients suffering from diabetes)		✓	

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HOW TO STORE IT

- Keep all medicines out of the reach of children.
- Capsules: Store at room temperature 15°C to 30°C, in tightly closed and light resistant containers.
- Tablets: Store at room temperature 15°C to 30°C. Protect from moisture.
- Do not use this medicine after the expiry date, which is printed on the package label.
- If your doctor tells you to stop taking APO-GABAPENTIN, or if you find that they have passed their expiry date, please return any leftover medicine to your pharmacist.

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.

MORE INFORMATION

If you want more information about APO-GABAPENTIN:

- 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>); the manufacturer's website <http://www.apotex.ca/products>, or by calling 1-800-667-4708.

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

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