

PART III: CONSUMER INFORMATION
PRO-GABAPENTIN
(gabapentin)

This leaflet is part III of a three-part “Product Monograph” published when PRO-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 PRO-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:**

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

What it does:

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

When it should not be used:

Do not use PRO-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 important nonmedicinal ingredients are:

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

What dosage forms it comes in:

PRO-GABAPENTIN is available in tablets (containing 600 mg or 800 mg of gabapentin).

WARNINGS AND PRECAUTIONS

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

- All your medical conditions, especially if you have any kidney disease.
- If you are taking any other medicines (prescription and nonprescription).
- 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.
- Your habits of alcohol consumption.
- If you drive a vehicle or perform hazardous tasks during your work.

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 morphine. Morphine may increase the levels of PRO-GABAPENTIN in your blood. If you experience increased side effects such as drowsiness or slowed breathing while taking these drugs together, the dose of PRO-GABAPENTIN or morphine may need to be adjusted.

PROPER USE OF THIS MEDICATION**Usual dose:**

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

Overdose:

If you have taken a large number of tablets all at once, contact your doctor or nearest hospital emergency department, even though you may not feel sick. Show the doctor your bottle of medication.

IMPORTANT: PLEASE READ

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 PRO-GABAPENTIN, contact your doctor or pharmacist.

Like all medications, PRO-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.
- Stop taking the drug and contact your doctor immediately if you experience any severe, unusual or allergic reactions (including skin rash or redness and/or breathing difficulties).
- When you first begin taking PRO-GABAPENTIN you may experience some side effects such as 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.
- Avoid alcoholic drinks while taking PRO-GABAPENTIN.
- The following side effects have been reported since gabapentin has been marketed. At this time it is unknown

whether or not these side effects were caused by the use of gabapentin. If you develop any of the following side effects tell your doctor immediately: skin rash or redness, blood glucose fluctuations for patients suffering from diabetes, chest pain, shortness of breath, hallucinations, unusual muscle movement or tone, heart palpitations, ringing or whistling in the ear, unusual changes in mood, sleeplessness, jaundice (yellowing of skin), dark urine, nausea and/or vomiting, swelling of legs, ankles or feet, and inability to control urination.

- Please see your doctor immediately if you develop fever, rash, swollen lymph nodes, hives, sore mouth, sore eyes or swelling of lips or tongue, particularly in the first six weeks of therapy.
- 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		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Common	Swelling of legs, ankles or feet.	*		
Uncommon	Heart palpitations		*	
	Chest pains		*	
	Jaundice (yellowing of skin)		*	
	Dark urine		*	
	Unusual muscle movement or tone; unexplained muscle pain or tenderness or weakness		*	
	Hallucinations			*
	Unusual changes in mood		*	
	Shortness of breath		*	

IMPORTANT: PLEASE READ

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

	Seizures			*
	Severe, unusual or allergic reactions (fever, rash, swollen lymph nodes, hives, sore mouth, sore eyes or swelling of lips or tongue)			*

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

HOW TO STORE IT

- Store at room temperature 15-30°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 PRO-GABAPENTIN, or if you find that they have passed their expiry data, please return any left over medicine to you pharmacist.

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

For more information, please contact your doctor, pharmacist or other healthcare professional.

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

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