

PART III: CONSUMER INFORMATIONPr **PRO-GABAPENTIN**

(Gabapentin Tablets USP)

600 mg and 800 mg

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 nonmedicinal ingredients are:

Copovidone, corn starch, hypromellose 5 cP, magnesium stearate, poloxamer 407, polyethylene glycol 400, polyethylene glycol 8000, polysorbate 80, talc and titanium dioxide.

What dosage forms it comes in:

Tablets, 600 mg and 800 mg

WARNINGS AND PRECAUTIONS**SERIOUS WARNINGS AND PRECAUTIONS**

Taking gabapentin with opioid medicines, alcohol, or other central nervous system depressants (including street

drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

BEFORE you use Pro-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 Pro-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 Pro-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 gabapentin in your blood.

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

Avoid alcoholic drinks while taking Pro-Gabapentin .

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 think you have taken too much Pro-Gabapentin, 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 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.
- When you first begin taking Pro-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		Seek Emergency Medical Attention
		Only if severe	In all cases	
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 hurting yourself		√	
	Jaundice: yellowing of skin, dark urine		√	

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	Only if severe	In all cases		
Rhabdomyolysis : Unusual muscle movement or tone; unexplained muscle pain or tenderness or weakness, dark urine, nausea and/or vomiting		√		
Incontinence: inability to control urination		√		
Ringing or whistling in the ears		√		
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)		√		

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

HOW TO STORE IT

- Keep all medicines out of the reach of children.
- Store tablets at controlled room temperature (15°C to 30°C).

- 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 date, please return any leftover medicine to your pharmacist.

MORE INFORMATION

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 (<http://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.

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

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