

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **PRO-GABAPENTIN**

Gabapentin Capsules

Read this carefully before you start taking **PRO-GABAPENTIN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PRO-GABAPENTIN**.

Serious Warnings and Precautions

Taking PRO-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.

What is PRO-GABAPENTIN used for?

PRO-GABAPENTIN is used in combination with other medications to treat epilepsy in adults.

How does PRO-GABAPENTIN work?

PRO-GABAPENTIN belongs to the family of medicines called antiepileptic drugs. It works by acting on the brain to help decrease the number of seizures you may have.

What are the ingredients in PRO-GABAPENTIN?

Medicinal ingredients: Gabapentin

Non-medicinal ingredients:

PRO-GABAPENTIN Capsules: Corn Starch, Gelatin, Lactose Anhydrous, Red Iron Oxide (400 mg), Talc, Titanium Dioxide and Yellow Iron Oxide (300 mg and 400 mg).

PRO-GABAPENTIN comes in the following dosage forms:

Capsules: 100 mg, 300 mg and 400 mg

Do not use PRO-GABAPENTIN if:

- You are allergic to gabapentin or to any other ingredient in PRO-GABAPENTIN.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRO-GABAPENTIN. Talk about any health conditions or problems you may have, including if you:

- Have mixed seizure disorders, or experience absence seizures (brief, sudden lapses of consciousness where you stare into space for a few seconds).
- Have any breathing or lung problems.

- Have any kidney problems.
- Are pregnant, think you may be pregnant or thinking about becoming pregnant.
- Are breast-feeding or plan to breastfeed. You and your healthcare professional should decide whether you should take PRO-GABAPENTIN or breastfeed, but you should not do both.
- Have a history of alcohol or drug abuse.
- Have a history of a psychiatric disorder.
- Drink alcohol on a regular basis.
- Are elderly (65 years of age or older).
- Drive a vehicle or perform hazardous tasks during your work.

Other warnings you should know about:

Stopping your treatment: Do NOT suddenly stop taking PRO-GABAPENTIN without talking to your healthcare professional first. If you do this, it may cause you to:

- have more seizures; or
- experience other withdrawal symptoms such as anxiety, sleeplessness, nausea, pain and/or sweating, shaking (tremor), headache, depression, dizziness or feeling abnormal or unwell. Stopping your treatment must be a gradual process that you discuss with your healthcare professional.

Dependence/Tolerance: Even when PRO-GABAPENTIN has been taken exactly as directed, there have been some cases of abuse, misuse, addiction, physical dependence and withdrawal. Your healthcare professional will monitor you while you are taking PRO-GABAPENTIN. If you feel like you are craving PRO-GABAPENTIN, or not using it as directed, talk to a healthcare professional right away.

Pregnancy: If you take PRO-GABAPENTIN during the first trimester of your pregnancy, your baby may be at risk for serious birth defects. Do not take PRO-GABAPENTIN if you are pregnant (or think you might be pregnant), unless advised by your healthcare professional. You must use an effective birth control method while taking PRO-GABAPENTIN if you are able to get pregnant. If you are planning on becoming pregnant, talk to your healthcare professional before taking PRO-GABAPENTIN.

Pregnancy registry: If you become pregnant while taking PRO-GABAPENTIN, talk to your healthcare professional 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 medicines during pregnancy. Information on the registry can also be found at the following website:

<http://www.aedpregnancyregistry.org/>.

Severe skin reactions: In very rare cases, skin reactions that can be serious or life-threatening have been reported. This includes skin conditions such as Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN), erythema multiforme (EM), and drug reaction with eosinophilia and systemic symptoms (DRESS). The following symptoms may be related to these skin reactions:

- Fever
- severe rash

- swollen lymph glands
- flu-like feeling
- blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body
- yellow skin or eyes
- shortness of breath
- dry cough
- chest pain or discomfort
- feeling thirsty
- urinating less often, less urine

Suicidal thoughts and behaviour: There have been reports that antiepileptic medications like PRO-GABAPENTIN may cause you to have thoughts of harming or killing yourself. If you have these thoughts at any time, contact a healthcare professional or go to a hospital right away. You may find it helpful to tell a relative or close friend how you are feeling and ask them to tell you if they notice any changes in your behaviour.

Driving and using machines: Do not drive at all if you have uncontrolled epilepsy. PRO-GABAPENTIN may cause you to feel dizzy or drowsy. Avoid driving, using machinery, or doing dangerous activities until you know how PRO-GABAPENTIN affects you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

- Do NOT take PRO-GABAPENTIN with opioid medicines, alcohol, or other central nervous system depressants (including street drugs). This can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

The following may also interact with PRO-GABAPENTIN:

- Aluminum and magnesium-based antacids.

How to take PRO-GABAPENTIN:

- Take PRO-GABAPENTIN exactly as your healthcare professional tells you to.
- Do NOT change your dose unless your healthcare professional tells you to.
- Do NOT stop taking PRO-GABAPENTIN suddenly, as this can increase the number of seizures you have.
- Take PRO-GABAPENTIN with or without food.

Usual dose:

Your healthcare professional will decide the best dose of PRO-GABAPENTIN for you. They may increase or decrease the dose depending on your response to the medication.

Overdose:

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

If you think you, or a person you are caring for, have taken too much PRO-GABAPENTIN, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

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 healthcare professional as soon as possible.

What are possible side effects from using PRO-GABAPENTIN?

These are not all the possible side effects you may have when taking PRO-GABAPENTIN. If you experience any side effects not listed here, tell your healthcare professional.

- Agitation
- Drowsiness
- Dizziness
- Lack of muscle coordination
- Fatigue
- Eye twitching
- Tremors
- Nausea
- Vomiting
- Breast enlargement (in men and women)

Call your healthcare professional immediately if your seizures get worse.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Edema: unusual swelling of the arms, hands, legs, feet and ankles, face or airway passages		✓	
UNCOMMON			
Allergic reaction: difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat			✓
Angina (chest pain): discomfort in the shoulder,		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
arm, back, throat, jaw or teeth, pain or pressure in the chest			
Behavior and mood changes: agitation including aggressive behavior or hostility, compulsive gambling, compulsive shopping, changes in sexual desire or sexual activity, increased eating		✓	
Hallucinations: seeing or hearing things that are not there			✓
Heart palpitations: fast-beating, fluttering or pounding of the heart		✓	
Incontinence: inability to control urination		✓	
Jaundice: yellowing of skin and eyes, dark urine, light-coloured stool, itching all over your body		✓	
Respiratory depression (also known as hypoventilation): slow, shallow or weak breathing, blue lips, fingers or toes, confusion, headaches.			✓
Rhabdomyolysis (breakdown of damaged muscle): muscle tenderness, weakness, red-brown (tea-coloured) urine		✓	
Seizures (fits): uncontrollable shaking with or without loss of consciousness		✓	
Suicidal thoughts or actions		✓	
Syncope (fainting): a temporary loss of consciousness due to a sudden drop in blood pressure.		✓	
Tinnitus (hearing problems): ringing, buzzing, clicking or hissing noise in the ears		✓	
UNKNOWN FREQUENCY			
Blood glucose fluctuations (for patients suffering from diabetes): increased thirst, frequent urination, headache, confusion, low energy		✓	
Confusion		✓	
Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue		✓	
Hypoglycemia (low blood sugar): increased thirst, frequent urination, hunger, nausea and dizziness, fast heartbeat, tingling, trembling, nervousness, sweating, low energy		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Hyponatremia (low sodium in the blood): lethargy, confusion, muscular twitching or worsening of convulsions		✓	
Severe skin reactions: fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine		✓	
Sleeplessness		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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.

Storage:

- Store between 15°C to 30°C.
- Keep out of reach and sight of children.

If you want more information about PRO-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>, or by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or medinfo@prodoc.qc.ca

This leaflet was prepared by Pro Doc Ltée.
Laval, Quebec, H7L 3W9

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