

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr PREGABALIN

Pregabalin Capsules

Read this carefully before you start taking **PREGABALIN** 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 **PREGABALIN**.

Serious Warnings and Precautions

Taking PREGABALIN with opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

What is PREGABALIN used for?

PREGABALIN is used in adults to treat pain caused by nerve damage due to:

- Diabetes
- Shingles
- Spinal cord injury

PREGABALIN is also used to treat pain associated with a condition called fibromyalgia (widespread pain).

How does PREGABALIN work?

PREGABALIN works by decreasing the number of nerve signals in your body. This helps to calm down oversensitive nerve cells, which helps to relieve pain.

What are the ingredients in PREGABALIN?

Medicinal ingredients: Pregabalin

Non-medicinal ingredients: pregelatinized starch, talc. Hard capsule contains: gelatin, ink and titanium dioxide or colloidal silicon dioxide, gelatin, glacial acetic acid, ink, sodium lauryl sulfate and titanium dioxide..

PREGABALIN comes in the following dosage forms:

Capsules: 25 mg, 50 mg, 75 mg, 150 mg, 225 mg or 300 mg.

Do not use PREGABALIN if:

- You are allergic to pregabalin, or any other ingredient in PREGABALIN.

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

- have any kidney problems.
- have any breathing problems or respiratory disease.
- are pregnant, plan to become pregnant, or think you might be pregnant.
- are breastfeeding. PREGABALIN passes into breast milk and it is not known if it can harm your baby. You and your healthcare provider should discuss whether you should take PREGABALIN or breast-feed, but you should not do both.
- have ever had an allergic reaction to any other drug.
- have a history of heart disease or heart failure.
- have a history of lower gastrointestinal problems (e.g., constipation, blocked or paralysed bowel), or you are taking medication(s) that may cause constipation.
- have current or a history of addiction or substance abuse, misuse, physical dependence or withdrawal.

Other warnings you should know about:

Pregnancy: PREGABALIN should not be taken during pregnancy. If you become pregnant while taking PREGABALIN, tell your healthcare professional **right away**. If you are taking PREGABALIN and are of childbearing age, you must use an effective method of birth control. If you take PREGABALIN during your first trimester of pregnancy, it can cause major birth defects in your unborn child.

Pregnancy Registry: If you become pregnant while taking PREGABALIN, 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 anticonvulsant medicines during pregnancy. Information on the registry can also be found at the website <http://www.aedpregnancyregistry.org/>.

Eye Problems: If you experience any changes in your vision while taking PREGABALIN, tell your healthcare professional right away. If you already have eye problems, your healthcare professional may recommend that you have more frequent eye exams.

Stopping Your Medication: Do NOT stop taking PREGABALIN without discussing it with your healthcare professional first. Stopping your treatment abruptly may cause you to experience unwanted side effects including insomnia, nausea, headache, anxiety, excessive sweating and diarrhea. Convulsions have occurred in non-epileptic patients.

Stopping your treatment must be a gradual process that you discuss with your healthcare professional. If you have any concerns with your treatment, talk to your healthcare professional.

Dependence/Tolerance: Even when pregabalin 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 PREGABALIN. If you feel like you are craving PREGABALIN, or not using it as directed, talk to a healthcare professional right away.

Driving and Using Machines: PREGABALIN may cause you to feel dizzy or sleepy. Wait until you know how PREGABALIN affects you before performing tasks that require special attention.

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 PREGABALIN 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 interact with PREGABALIN:

- Alcohol
- Opioid medicines
- Benzodiazepines
- Medications used to treat diabetes, such as rosiglitazone, pioglitazone

How to take PREGABALIN:

- Take PREGABALIN exactly as your healthcare professional has told you to.
- Do NOT stop taking PREGABALIN abruptly or you may experience unwanted side effects. If you have concerns with your treatment, talk to your healthcare professional first.
- You can take PREGABALIN with or without food.

Usual dose:

Your healthcare professional has decided the best dose for you and will tell you how much to take and when to take it.

Overdose:

If you think you, or a person you are caring for, have taken too much PREGABALIN, contact a healthcare professional, hospital emergency department, or regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669 immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose by a few hours, take it as soon as you remember. If it is close to your next dose, do NOT take the missed capsules. Simply wait and restart PREGABALIN with your next scheduled dose.

What are possible side effects from using PREGABALIN?

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

Side effects may include:

- Dizziness
- Sleepiness
- Headache
- Nausea
- Dry mouth
- Increased cough
- Weight gain
- Trouble concentrating
- Forgetfulness
- Lack of energy
- Muscle weakness
- Constipation; talk with your healthcare professional about ways to prevent constipation when you start using PREGABALIN

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			
Blurred vision		✓	
UNCOMMON			
Edema: unusual swelling of the arms, hands, legs, feet and ankles, face or airway passages		✓	
Angiodema: swelling of the face, mouth, lips, gums, neck or throat, trouble breathing, diarrhea, nausea or vomiting			✓
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			✓
Decrease in the amount of urine		✓	
Suicidal thoughts or actions		✓	
RARE			

Kidney Failure: confusion, itchiness or rashes, puffiness in your face and hands, swelling in your feet or ankles, decreased amount of urine, weight gain		✓	
UNKNOWN			
Respiratory Depression (also known as hypoventilation): slow, shallow or weak breathing, blue lips, fingers or toes, confusion, headaches			✓
VERY RARE			
Seizures (fits): uncontrollable shaking with or without loss of consciousness.			✓
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			✓

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 at room temperature (15°C to 30°C) in the package it came in.

Keep PREGABALIN out of reach and sight of children.

If you want more information about PREGABALIN:

- 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 www.sivem.ca, or by calling 1-855-788-3153.

This leaflet was prepared by Sivem Pharmaceuticals ULC.

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