

PART III: CONSUMER INFORMATION

P^rPREGABALIN
Pregabalin Capsules

This leaflet is part III of a three-part "Product Monograph" published when PREGABALIN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PREGABALIN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What is the most important information I should know about PREGABALIN?

1. PREGABALIN may cause serious allergic reactions. Call your doctor right away if you think you have any of the following symptoms of a serious allergic reaction:
 - swelling of the face, mouth, lips, gums, tongue or neck
 - have any trouble breathing
 - other allergic reactions may include rash, hives and blisters.
2. PREGABALIN may cause dizziness and sleepiness.
 - Do not drive a car, work with machines, or do other dangerous activities until you know how PREGABALIN affects how alert you are. Ask your doctor when it is okay to do these activities.
3. PREGABALIN may cause problems with your eyesight, including blurry vision. Call your doctor if you have any changes in your eyesight.

What the medication is used for:

PREGABALIN is a prescription medicine used for the symptomatic relief of neuropathic pain associated with:

- Diabetic peripheral neuropathy (Pain from damaged nerves due to diabetes)
- Postherpetic neuralgia (Persisting pain following rash due to shingles)
- Pain from damaged nerves in the spinal cord
- PREGABALIN is also used for the symptomatic relief of pain associated with fibromyalgia (a condition which includes widespread pain).

What it does:

PREGABALIN can relieve pain. Some patients taking pregabalin showed improvement as early as the first week of treatment.

When it should not be used:

You should not take PREGABALIN if you are allergic to pregabalin, the main ingredient in PREGABALIN, or any other

ingredient in PREGABALIN (see “What the non-medicinal ingredients are”). Children under the age of 18 years.

What the medicinal ingredient is:

Pregabalin

What the nonmedicinal ingredients are:

Each capsule of PREGABALIN contains 25 mg, 50 mg, 75 mg, 150 mg, 225 mg, or 300 mg of pregabalin and the following nonmedicinal ingredients: ammonium hydroxide, gelatin, iron oxide black, pregelatinized starch, propylene glycol, shellac glaze, talc, titanium dioxide. In addition the 75, 225 and 300 mg strengths contain also red iron oxide.

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS

SERIOUS WARNINGS AND PRECAUTIONS

Taking PREGABALIN 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 PREGABALIN tell your doctor or pharmacist if:

- you are taking any other prescription medicines including narcotic pain medicines like oxycodone, non-prescription medicines, or natural / herbal remedies.
- you have any kidney problems.
- you are pregnant, plan to become pregnant, or think you might be pregnant.
- you 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.
- you have ever had an allergic reaction (itching, wheezing, hives, or swelling of the throat or face) to pregabalin or any of the nonmedicinal ingredients listed in “What the nonmedicinal ingredients are”:
- you have a history of heart disease called congestive heart failure.
- you have a history of lower gastrointestinal problems e.g., constipation, blocked or paralysed bowel), or you are taking medication(s) that may cause constipation.

Pregnancy Registry: If you become pregnant while taking PREGABALIN, talk to your doctor 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. Any woman who is currently pregnant and is taking antiepileptic

drugs for any reason, can enroll in the registry. Information on the registry can also be found at the website <http://www.aedpregnancyregistry.org/>.

INTERACTIONS WITH THIS MEDICATION

While you are taking PREGABALIN, don't start any new medicines, including natural or herbal medicines, without talking to your doctor first. Your doctor or pharmacist will know which medicines are safe for you to take together. PREGABALIN does not interfere with birth control pills.

You may have a higher chance for dizziness and sleepiness if the following drugs are taken with PREGABALIN:

- Alcohol
- Medicines for anxiety (such as lorazepam)
- Narcotic pain medicine (such as oxycodone)
- Any medicines that make you sleepy

You may have a higher chance of weight gain or swelling if the antidiabetic pills, Avandia (rosiglitazone) or Actos (pioglitazone) are taken with PREGABALIN.

PROPER USE OF THIS MEDICATION

You can take PREGABALIN with or without food. Avoid alcoholic drinks while taking PREGABALIN.

Usual adult dose:

Your doctor will tell you how much to take and when to take it.

Overdose:

In case of a drug overdose, immediately go to the nearest emergency room even if you do not feel sick. Make sure you take your medicine bottle with you to show the doctor.

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.

Do not suddenly stop taking PREGABALIN. Talk to your doctor first. Plan ahead to have a refill so you don't run out.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Some patients may have side effects while taking PREGABALIN. Side effects are usually mild. In studies, few patients stopped taking PREGABALIN due to side effects.

The most common side effects were: dizziness, sleepiness, blurred vision, dry mouth, swelling of the extremities, weight

gain, trouble concentrating, lack of energy, muscle weakness, constipation, and forgetfulness.

A small number of patients taking a drug of this type may experience thoughts of suicide. Your doctor should be informed immediately if this occurs.

When you start PREGABALIN, you may get sleepy or experience dizziness. Avoid potentially hazardous tasks: do not drive a car or operate machinery until you are sure that this medication does not affect your ability to drive or operate machinery or until you get used to PREGABALIN.

When PREGABALIN is taken with other medications that may cause constipation (such as opioid pain medications), it is possible that gastrointestinal problems may occur (e.g., constipation, blocked or paralysed bowel).

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 emergency medical assistance
		Only if severe	In all cases	
Common	Dizziness	✓		
	Sleepiness	✓		
	Blurred vision		✓	
Uncommon	Weight gain	✓		
	Swelling of hands and feet (edema)		✓	
	Swelling of the face, mouth, lips, gums, neck or throat, trouble breathing			✓
	Extreme fatigue		✓	
	Increased cough		✓	
	Allergic reactions (skin rash, hives, blisters)			✓
	Decrease in the amount of urine		✓	
Thoughts of suicide		✓		
Very rare	Seizures			✓

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

HOW TO STORE IT

Keep PREGABALIN out of reach and sight of children. Store it at room temperature (15°C to 30°C) in the package it came in.

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 PREGABALIN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>); the manufacturer's website www.sivem.ca, or by calling 1-855-788-3153.

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