

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**Pr** **PRO-LEVETIRACETAM – 250**

**Pr** **PRO-LEVETIRACETAM – 500**

**Pr** **PRO-LEVETIRACETAM – 750**

#### **Levetiracetam Tablets**

Read this carefully before you start taking **PRO-LEVETIRACETAM** 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-LEVETIRACETAM**.

#### **What is PRO-LEVETIRACETAM used for?**

PRO-LEVETIRACETAM is used in adults to help reduce the number of seizures. It is to be used with other seizure medicines.

#### **How does PRO-LEVETIRACETAM work?**

PRO-LEVETIRACETAM belongs to the family of medicines called antiepileptics for treating epilepsy. The exact way that PRO-LEVETIRACETAM works to treat seizures is not known.

#### **What are the ingredients in PRO-LEVETIRACETAM?**

Medicinal ingredients: levetiracetam

Non-medicinal ingredients: anhydrous citric acid, colloidal silicon dioxide, copovidone, ferric oxide red (750 mg only), ferric oxide yellow (500 mg and 750 mg), hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyethylene glycol and titanium dioxide.

#### **PRO-LEVETIRACETAM comes in the following dosage forms:**

Film-coated tablets: 250 mg, 500 mg and 750 mg.

#### **Do not use PRO-LEVETIRACETAM if:**

- you are allergic to levetiracetam or to any of the other ingredients in PRO-LEVETIRACETAM (see [What are the ingredients in PRO-LEVETIRACETAM?](#)).

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRO-LEVETIRACETAM. Talk about any health conditions or problems you**

**may have, including if you:**

- have any health problems, including ones you have had in the past
- have kidney disease
- have had to ever shown unusual sensitivity (rash or any other signs of allergy) to any other antiepileptic drugs
- have recurrent infections or blood coagulation disorders
- have or have had a history of any heart problems or problems with the way your heart beats
- take any medicines that affect the heart or how it beats
- are pregnant or thinking about becoming pregnant. Taking more than one antiepileptic medication during pregnancy increases the risk of birth defects.
  - You and your healthcare professional will have to decide if PRO-LEVETIRACETAM is right for you while you are pregnant
  - If you use PRO-LEVETIRACETAM while you are pregnant, ask your healthcare provider about joining the North American Antiepileptic Drug Pregnancy Registry by calling 1-888-233-2334 (toll free). Women who are pregnant and planning to take PRO-LEVETIRACETAM should call the pregnancy registry. It will enable the collection of valuable data about PRO-LEVETIRACETAM use in pregnancy
- are breastfeeding or planning to breastfeed. PRO-LEVETIRACETAM is known to pass into breast milk and may harm your baby. You and your healthcare professional should decide whether you should take PRO-LEVETIRACETAM or breastfeed, but not both
- are 65 years of age or older
- have severe liver problems
- are of Japanese descent
- have seizures associated with a particular genetic mutation called SCN8A mutation. Ask your healthcare professional if you are unsure

**Other warnings you should know about:**

**Driving and Operating Machinery:** PRO-LEVETIRACETAM may affect your coordination and make you feel sleepy and tired. You should not drive or operate machinery until you know how PRO-LEVETIRACETAM affects you.

**Changes in behaviour:** You should pay attention to any mental changes, especially sudden changes in your mood, behaviours, thoughts, or feelings. Call your healthcare professional **right away**, if you have any changes in behaviour that are new, worse, or worry you. These changes could include:

- feeling depressed, nervous, or anxious;
- feeling angry, agitated or hostile;

- in some people, psychotic symptoms, such as hallucinations (seeing or hearing things that are not really there); delusions (false or strange thoughts or beliefs), and unusual behaviour.

A small number of people may have thoughts of suicide (harming or killing themselves) when taking antiepileptic drugs such as PRO-LEVETIRACETAM. If at any time you have these thoughts, get medical help right away. **Do NOT** stop PRO-LEVETIRACETAM on your own.

### **Severe Allergic Reaction Involving the Skin and other Organs:**

There is no way to tell if a mild skin rash will become a severe reaction. The following serious skin reactions have been reported with levetiracetam:

- Stevens-Johnson Syndrome (SJS)
- Toxic Epidermal Necrolysis (TEN)
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

Although very rare, severe forms of these reactions may lead to death.

Get help **right away** if you develop any combination of the following:

- a rash or any serious skin reaction such as blistering or peeling of the lips, eyes or mouth
- fever
- swollen glands
- joint pain
- problems related to the liver, kidneys, heart, lungs or other organs
- allergic reactions (anaphylaxis or angioedema) such as swelling of the face, lips, eyes, tongue, and throat, trouble swallowing or breathing, and hives

**Worsening Seizures:** Your seizures may get worse:

- when you begin your treatment with PRO-LEVETIRACETAM, or your dose is increased;
- if you take PRO-LEVETIRACETAM to treat seizures associated with a particular genetic mutation (i.e., SCN8A mutation). PRO-LEVETIRACETAM may also be ineffective in treating these seizures.

Tell your healthcare professional if you notice your seizures remain present. If they get worse, tell your healthcare professional **right away**.

See the "[Serious side effects and what to do about them](#)" table, below, for more information on these and other serious side effects.

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

**The following may interact with PRO-LEVETIRACETAM:**

- Other antiepileptic medicines (such as carbamazepine, topiramate)
- Methotrexate (used to treat certain types of cancer and arthritis)
- Oral contraceptives (used for birth control)

**How to take PRO-LEVETIRACETAM:**

- Take PRO-LEVETIRACETAM exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Take PRO-LEVETIRACETAM in the morning and in the evening at about the same time each day.
- PRO-LEVETIRACETAM can be taken with or without food.
- Swallow the tablets with water.
- After taking PRO-LEVETIRACETAM you may have a bitter taste in your mouth.

**Remember: This medicine has been prescribed only for you. Do not give it to anybody else.**

**Usual dose:**

- The usual starting dose of PRO-LEVETIRACETAM is 500 mg twice a day, once in the morning and once in the evening.
- Based on your response and your tolerability, your healthcare professional may increase your daily dose.
- Your healthcare professional may prescribe you a different dose if you have problems with your kidneys.

**Stopping treatment:** If your healthcare professional decides to stop your treatment with PRO-LEVETIRACETAM, they will decrease the dose slowly. This is to help prevent your symptoms from coming back again or becoming worse.

- **Do NOT** stop taking PRO-LEVETIRACETAM unless your healthcare professional has told you to. Stopping a seizure medicine suddenly can cause you to have seizures that will not stop (status epilepticus). This can be very serious.
- Never change the dose yourself

## Overdose:

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

## Missed Dose:

If you forget to take a dose, take it as soon as you remember, and then go on as usual. However, if it is almost time for your next dose, skip the dose you forgot and continue with your next scheduled dose. **Do not take two doses at the same time.**

## What are possible side effects from using PRO-LEVETIRACETAM?

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

The most frequently observed side effects are:

- sleepiness
- lack or loss of strength
- infection (such as a common cold)
- dizziness

Other side effects include:

- vertigo (sensation of rotation)
- loss of memory (amnesia)
- bruising
- toothache
- sore throat, runny nose, stuffed nose/head (sinusitis)
- hair loss (alopecia)
- headache

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	
<b>UNCOMMON</b>			
Thoughts of suicide or hurting yourself			✓
<b>RARE</b>			

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	
Extreme sleepiness and tiredness and/or difficulty coordinating muscles normally		✓	
<b>Mood and Behaviour changes:</b> aggression, agitation, anger, anxiety, apathy (lack of enthusiasm), depression, hostility, mood swings, personality disorder, nervousness / irritability, repeated unwanted thoughts or sensations or the urge to do something over and over again		✓	
<b>Serious skin reactions (Stevens - Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)):</b> any combination of itchy skin rash, redness, blistering and peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands, joint pain, yellowing of the skin or eyes, dark urine			✓
<b>Severe allergic reactions:</b> swelling of the face, eyes, or tongue, difficulty swallowing, wheezing, hives and generalized itching, rash, fever, abdominal cramps, chest discomfort or tightness, difficulty breathing, unconsciousness			✓
Worsening seizures			✓

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	
<b>UNKNOWN FREQUENCY</b>			
<b>Psychotic symptoms:</b> hallucination (seeing or hearing things that are not really there), delusions (false or strange thoughts or beliefs), paranoia (intense feeling of distrust, fear of persecution) and unusual behaviour		✓	
<b>Rhabdomyolysis:</b> (breakdown of damaged muscle): muscle tenderness, weakness, red-brown (tea-coloured) urine			✓
<b>Neuroleptic Malignant Syndrome (more common in people of Japanese descent):</b> pronounced muscle stiffness or inflexibility with high fever, rapid or irregular heartbeat, sweating, state of confusion or reduced consciousness			✓
<b>Liver disorder:</b> nausea, vomiting, loss of appetite combined with itching, yellowing of the skin or eyes, dark 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 tablets between 15°C-30°C.

Keep out of reach and sight of children.

### **If you want more information about PRO-LEVETIRACETAM:**

- 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 (<http://www.apotex.ca/products>), or by contacting Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [medinfo@prodoc.qc.ca](mailto:medinfo@prodoc.qc.ca).

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