

PART III: CONSUMER INFORMATION

Pr **SANDOZ® LEVETIRACETAM**
 Levetiracetam Tablets
 250 mg, 500 mg, 750 mg, 1000 mg

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

ABOUT THIS MEDICATION

What the medication is used for:

Sandoz Levetiracetam is a prescription medicine used to help reduce the number of seizures when taken together with other seizure medicines, in adults 18 years and older.

What it does:

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

When it should not be used:

Do not take Sandoz Levetiracetam if you are allergic to levetiracetam or any of the other ingredients in Sandoz Levetiracetam listed in the “nonmedicinal ingredients” section below.

What the medicinal ingredient is:

levetiracetam

What the nonmedicinal ingredients are:

Non-medicinal ingredients: povidone, microcrystalline cellulose, croscarmellose sodium, crospovidone, colloidal silicon dioxide anhydrous, talc and magnesium stearate. In addition, the film coating contains the following inactive ingredients: hypromellose, hydroxypropylcellulose, macrogol, titanium dioxide, talc, indigo carmine (250 mg tablet), yellow iron oxide (500 mg tablet) and yellow iron oxide and red iron oxide (750 mg tablet).

What dosage forms it comes in:

250 mg, 500 mg, 750 mg and 1000 mg film-coated tablets.

WARNINGS AND PRECAUTIONS

Because Sandoz Levetiracetam can affect your mental alertness and coordination, it is very important not to perform any potentially hazardous tasks such as driving a car or operating machinery until you know how Sandoz Levetiracetam affects you.

A small number of people may have thoughts of suicide (harming or killing themselves) when taking antiepileptic drugs such as Sandoz Levetiracetam. If at any time you have these thoughts, immediately contact your doctor. **Do not discontinue Sandoz 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. Serious skin reactions known as Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) have been reported with levetiracetam. Although very rare, severe forms of these reactions may lead to death. Seek immediate medical attention if you develop any combination of:

- 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.

BEFORE you use Sandoz Levetiracetam talk to your doctor or pharmacist if:

- you have any health problems, including ones you have had in the past;
- you have kidney disease;
- you have ever shown unusual sensitivity (rash or any other signs of allergy) to any other antiepileptic drugs;
- you are taking any medication, including ones you can get without a prescription;
- you have recurrent infections or blood coagulation disorders;
- you are pregnant or thinking about becoming pregnant. Taking more than one antiepileptic medication during pregnancy increases the risk of birth defects. You and your doctor will have to decide if Sandoz Levetiracetam is right for you while you are pregnant. If you use Sandoz Levetiracetam while you are pregnant, ask your healthcare provider about joining the North American Antiepileptic Drug Pregnancy Registry by calling (888) 233-2334 (toll free). Women who are pregnant and planning to take Sandoz Levetiracetam should call the pregnancy registry to enable collection of valuable data about Sandoz Levetiracetam use in pregnancy;
- you are breastfeeding. Levetiracetam is known to pass into breast milk and may harm your baby. You

and your doctor should decide whether you should Sandoz Levetiracetam or breastfeed, but not both.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor about all the medicines you take including prescription or non-prescription medicines, vitamins or herbal supplements. Sandoz Levetiracetam and other medicines may affect each other.

If you are a female patient taking an oral contraceptive, watch for irregular menstruation or spotting and immediately report such occurrences to your doctor as this may be an indication that the oral contraceptive may not be working properly and you may get pregnant.

Tell your doctor if you are taking a drug called methotrexate, used to treat certain types of cancer, severe psoriasis, and rheumatoid arthritis. Taking Sandoz Levetiracetam and methotrexate together can be harmful.

PROPER USE OF THIS MEDICATION

Usual Adult Dose:

Sandoz Levetiracetam tablets are taken orally twice a day, once in the morning and once in the evening, at about the same time each day. The treatment with Sandoz Levetiracetam usually starts with a dose of 1000 mg given half (500 mg) in the morning and half (500 mg) in the evening. After two weeks your dose may be increased. The typical daily maintenance dose is between 1000 mg and 3000 mg.

Your doctor may use a different dose if you have problems with your kidneys.

Sandoz Levetiracetam can be taken with or without food. After administration, the bitter taste of levetiracetam may be experienced.

If your doctor decides to stop your treatment with Sandoz Levetiracetam, he/she will decrease the dose step by step. This is to prevent your symptoms from coming back again or becoming worse.

It is very important that you take Sandoz Levetiracetam exactly as your doctor has instructed. Do not stop taking it abruptly. Never change the dose yourself. Do not stop taking Sandoz Levetiracetam or any other seizure medicine unless your healthcare provider told you to. Stopping a seizure medicine all at once can cause seizures that will not stop (status epilepticus), a very serious problem.

Tell your healthcare provider if your seizures get worse or if you have any new types of seizures.

Remember: This medicine has been prescribed only for you. Do not give it to anybody else. If you require any further information or advice, please consult your doctor or pharmacist.

Overdose:

In case of drug overdose, contact a health care practitioner, 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 go on as usual. **Do not take two doses at the same time.**

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most frequently observed side effects are:

- sleepiness
- weakness
- infection (such as a common cold)
- dizziness

Other side effects include:

- mood and behaviour changes such as anxiety, irritability or anger, depression, nervousness, personality disorder, and hostility
- lack of coordination
- vertigo (sensation of rotation)
- abnormal thinking
- loss of memory (amnesia)
- bruising
- toothache
- sore throat, runny nose, stuffed nose/head (sinusitis)

Some people may experience extreme sleepiness and tiredness and difficulty coordinating muscles normally.

Hair loss (alopecia) has been reported; in several cases when Sandoz Levetiracetam was discontinued, the hair grew back.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Side Effect/ Symptom	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Side Effect/ Symptom		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Uncommon	Thoughts of suicide or hurting yourself			✓
Rare	Severe Allergic Reactions: 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.			✓
	Serious skin reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, Drug Reaction with Eosinophilia and Systemic Symptoms): 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			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Side Effect/ Symptom		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
	skin or eyes, dark urine.			
	Extreme sleepiness and tiredness and/or difficulty coordinating muscles normally.		✓	
	Mood and behaviour changes such as anxiety, irritability or anger, depression.		✓	
	Rhabdomyolysis: Muscle pain or weakness, dark urine			✓

This is not a complete list of side effects. For any unexpected effects while taking Sandoz Levetiracetam, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (15-30°C). Keep well out of reach and sight of children.

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.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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

This document, plus the full product monograph, prepared for health professionals, can be obtained by contacting the sponsor, Sandoz Canada Inc., at: 1-800-361-3062

Or

by written request at:

110, Rue de Lauzon Boucherville, Québec, Canada, J4B 1E6

Or by e-mail at: medinfo@sandoz.com

This leaflet was prepared by Sandoz Canada Inc.

Last revised: November 28, 2018