

**PART III: CONSUMER INFORMATION**

**Pr Sandoz® Lacosamide**  
**Lacosamide**

**50 mg, 100 mg, 150 mg and 200 mg film-coated tablets**

**This leaflet is part III of a three-part “Product Monograph” published when Sandoz Lacosamide 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 Lacosamide. Contact your doctor or pharmacist if you have any questions about the drug.**

**ABOUT THIS MEDICATION**

**What the medication is used for:**

Sandoz Lacosamide is a prescription medicine used to treat partial-onset seizures when taken on its own or together with other seizure medicines in adults 18 years and older.

**What it does:**

Sandoz Lacosamide works in the brain to block the spread of seizure activity. The precise way that lacosamide tablet works to treat partial-onset seizures is unknown.

**When it should not be used:**

Do not take Sandoz Lacosamide if:

- you are allergic to lacosamide or any of the other ingredients in Sandoz Lacosamide tablets listed in the “nonmedicinal ingredients” section below.
- you suffer or have suffered in the past from a certain type of heart rhythm disorder (second or third degree AV block)

**What the medicinal ingredient is:**

Lacosamide

**What the nonmedicinal ingredients are:**

**Sandoz Lacosamide Tablets nonmedicinal ingredients:** microcrystalline cellulose, crospovidone, hydroxypropyl cellulose, low-substituted hydroxypropyl cellulose, colloidal silicon dioxide, magnesium stearate, hypromellose, polyethylene glycol, talc, titanium dioxide, and dye pigments:

**50 mg tablets:** FD&C Blue #2 aluminum lake, iron oxide red, iron oxide black

**100 mg tablets:** iron oxide yellow

**150 mg tablets:** iron oxide yellow, iron oxide red, iron oxide black

**200 mg tablets:** FD&C Blue #2 aluminum lake

**What dosage forms it comes in:**

Film-coated tablets: 50 mg, 100 mg, 150 mg and 200 mg

**WARNINGS AND PRECAUTIONS**

Sandoz Lacosamide may cause dizziness and poor coordination which could increase the risk of accidental injury or a fall. Therefore, you should be careful until you are used to the effects this medicine might have.

Do not drive, operate complex machinery, or engage in other hazardous activities until you know how Sandoz Lacosamide affects you. Ask your doctor when it is okay to do these activities.

Sandoz Lacosamide may cause double vision and blurred vision. If you experience visual disturbances while taking Sandoz Lacosamide, notify your doctor.

A small number of people being treated with anti-epileptics such as Sandoz Lacosamide have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

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

- you have any health problems, including ones you have had in the past;
- you have kidney or liver disease
- you are taking any medication, including ones you can get without a prescription;
- you are taking any medicine which can cause an abnormality on the ECG (electrocardiogram) called increased PR interval or heart block, for example medicines used to treat certain types of irregular heart beat or heart failure. If you are not sure that the medicines you are taking could have this effect, discuss this with your doctor (e.g. carbamazepine, pregabalin, lamotrigine, eslicarbazepine, beta-blockers, class I antiarrhythmic drugs, etc.)
- patients with pacemaker problems
- you suffer from a severe heart disease such as heart rhythm disorder, heart failure or heart attack;
- **you are pregnant or plan to become pregnant. It is not known if Sandoz Lacosamide may harm your unborn baby. You and your doctor will have to decide if Sandoz Lacosamide is right for you while you are pregnant. If you use Sandoz Lacosamide 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 Lacosamide should call the pregnancy registry to enable collection of valuable data about lacosamide tablets use in pregnancy. Information on the registry can also be found at the following website: <http://www.aedpregnancyregistry.org/> ;**
- you are breastfeeding. It is not known if lacosamide passes into breast milk and if it can harm your baby. You and your doctor should decide whether you

## IMPORTANT: PLEASE READ

should take Sandoz Lacosamide or breastfeed, but not both.

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

### INTERACTIONS WITH THIS MEDICATION

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

- any medicines that make you sleepy or dizzy
- any medications to treat a heart condition
- carbamazepine, pregabalin, lamotrigine, eslicarbazepine, beta-blockers, class I antiarrhythmic drugs, etc.

### PROPER USE OF THIS MEDICATION

#### Sandoz Lacosamide film-coated tablets:

- Sandoz Lacosamide may taken with or without food.
- Swallow the tablets whole with plenty of water. Do not chew or crush tablets.

#### Usual Dose:

Sandoz Lacosamide must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

#### When you take Sandoz Lacosamide on its own:

The treatment with Sandoz Lacosamide usually starts with 100 mg in the morning and 100 mg in the evening (200 mg a day). After one week your dose may be increased. The daily maintenance dose is between 200 mg and 600 mg.

#### When you take Sandoz Lacosamide with other seizure medicines:

The treatment with Sandoz Lacosamide tablets usually starts with 50 mg in the morning and 50 mg in the evening (100 mg a day). After one week your dose may be increased. The daily maintenance dose is between 200 mg and 400 mg.

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

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

Do not stop taking Sandoz Lacosamide 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.

#### Overdose:

If you think you have taken too much Sandoz Lacosamide, contact your health care professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms. Make sure you take your medicine 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, take Sandoz Lacosamide at your next regular time. Do not take two doses at the same time to make up for the missed dose.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects associated with the use of Sandoz Lacosamide are:

- dizziness, poor coordination
- headache
- nausea, vomiting, fatigue
- blurred vision, double vision

If you are elderly (older than 65), you may have a higher chance of the following side effects:

- falling
- diarrhea
- tremors/shaking

Tell your doctor about any side effect that bothers you or that does not go away.

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

Symptom / effect	Talk with your doctor or pharmacist		Seek Emergency Medical Attention
	Only if severe	In all cases	
Uncommon	Thoughts of suicide or hurting yourself		√
	Allergic reaction: swelling in the mouth, tongue, face and throat, itching, rash		√

*Canada Vigilance Program does not provide medical advice.*

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

	<b>Heart rhythm problems:</b> irregular pulse, slow pulse, rapid pulse, palpitations, shortness of breath, feeling lightheaded, fainting			√
Rare	Allergic reactions that typically present with fever, rash and swollen lymph nodes, and may be associated with signs and symptoms involving other organs, e.g. liver.			√
	<b>Liver disorder or liver injury:</b> itching, right upper belly pain, dark urine, yellow skin or eyes, unexplained flu-like symptoms			√

**MORE INFORMATION**

Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>) or the sponsor, Sandoz Canada Inc. ([www.sandoz.com](http://www.sandoz.com)) or by calling 1-800-361-3062

or by written request at:  
110, rue de Lauzon  
Boucherville, (QC), Canada  
J4B 1E6

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

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

**HOW TO STORE IT**

- Store Sandoz Lacosamide at room temperature, 15 to 30°C.
- Keep Sandoz Lacosamide and all medicines out of the reach and sight of children.

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/healthcanada/services/drugs-health-products/medeffectcanada/adverse-reaction-reporting.html>.
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 1908C  
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at <https://www.canada.ca/en/healthcanada/services/drugs-health-products/medeffectcanada/adverse-reaction-reporting.html>.

*NOTE: Should you require information related to the management of side effects, contact your health professional. The*