

PART III: CONSUMER INFORMATION

^{Pr}Sandoz Rivastigmine Rivastigmine Hydrogen Tartrate Capsules

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

Patients and/or Caregivers should read this leaflet before using Sandoz Rivastigmine. Remember, this information does not take the place of your doctor's instructions.

ABOUT THIS MEDICATION

What the medication is used for:

Sandoz Rivastigmine is one of a group of drugs known as "cholinesterase inhibitors" which is used for the treatment of the symptoms of patients with mild to moderate Alzheimer's disease or with dementia occurring at least 2 years following the diagnosis of Parkinson's disease. Although there are differences between the two types of dementias in terms of changes to the brain and to mental function, it is known that with both conditions there are decreased levels of acetylcholine, a substance which is found in the brain and which is thought to be necessary for good cognitive function (memory and other mental function).

The symptoms include progressive memory loss, increasing confusion and behavioural changes, as a result of which it becomes more and more difficult to carry out activities of daily living.

This medication should only be taken after proper diagnosis of your condition has been made by your doctor.

What it does:

People with Alzheimer's disease have decreased levels of acetylcholine, a substance which is found in the brain and which is thought to be necessary for memory and other mental functions. Sandoz Rivastigmine works by inhibiting an enzyme (acetylcholinesterase) which breaks down acetylcholine. This in turn increases the amount of acetylcholine in the brain. Sandoz Rivastigmine is a treatment of symptoms, not a cure of the disease. In clinical studies with Sandoz Rivastigmine, most patients with Alzheimer's disease had improved memory and other mental functions, or showed no further decline, as compared to placebo (sugar tablet) for up to 6 months. However, Sandoz Rivastigmine may take as long as 12 weeks to begin working, and patient response to this medicine will vary.

When it should not be used:

If any of the following conditions apply to you, tell your doctor and do not use Sandoz Rivastigmine

- If you know that you are allergic (hypersensitive) to

rivastigmine (including rivastigmine patch) or to any of the other substances listed in this leaflet (see 'What the nonmedicinal ingredients are'),

- If you have ever had an allergic reaction to a similar type of medicine,
- If you have severe liver problems.
- If you have had a previous allergic skin reaction with rivastigmine patch that spread beyond the patch size and/or if there was a more severe reaction at the patch site (such as blisters, increasing skin inflammation, swelling) that did not improve within 48 hours after removal of the transdermal patch
- If you have had severe rash on large areas of your body or blistering of the skin, mouth, eyes, or genitals when taking Sandoz Rivastigmine transdermal patch or capsules.

Sandoz Rivastigmine should only be used if prescribed to you by your doctor.

What the medicinal ingredient is:

Sandoz Rivastigmine contains the active substance rivastigmine hydrogen tartrate.

What the nonmedicinal ingredients are:

Sandoz Rivastigmine capsules contain the following inactive substances: hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose and silicon dioxide. The capsule shell is made of gelatin with red and/or yellow iron oxide and titanium dioxide. The printing ink is based on red iron oxide.

What dosage forms it comes in:

Capsules: Each hard gelatin capsule contains 1.5, 3.0, 4.5 or 6.0 mg of rivastigmine as rivastigmine hydrogen tartrate.

WARNINGS AND PRECAUTIONS

BEFORE you use Sandoz Rivastigmine talk to your doctor of pharmacist if:

- you have, or ever had irregular heartbeat
- you have, or ever had asthma or a severe respiratory disease;
- you have, or ever had seizures (fits or convulsions);
- you have a history of stomach ulcers or have an increased risk of developing ulcers (for example you are taking non-steroidal anti-inflammatory drugs (NSAIDs) or high doses of acetylsalicylic acid [ASA];
- you have a low body weight (less than 50 kg);
- you have, or ever had difficulties in passing urine;
- you have, or ever had liver or kidney problems;
- you have, or ever had inflammation of the pancreas;
- you are pregnant, planning on becoming pregnant, or breast feeding.
- you suffer from trembling;
- you have fainting episodes
- you experience gastro-intestinal reactions such as severe nausea (feeling sick), vomiting (being sick) and diarrhea. You

may become dehydrated (losing too much fluid) if vomiting or diarrhea are prolonged.

Talk to your doctor right away if you have skin inflammation, blisters or swelling of the skin that are increasing and spreading.

Your doctor will determine whether you can take Sandoz Rivastigmine and how closely you will need to be monitored while you are on this medicine.

Can I drive vehicles and operate machinery?

Your doctor will tell you whether your illness allows you to drive vehicles and operate machinery safely. If you feel dizzy or drowsy, do not drive, use machines or perform any other tasks that require your attention.

INTERACTIONS WITH THIS MEDICATION

Make sure your doctor knows if you are taking, have recently taken, or begin to take, any other medicines, including drugs, or herbal (natural) products that you can buy without a prescription.

Sandoz Rivastigmine should not be given at the same time as other medicines with similar effects (cholinomimetic agents) or with anticholinergic medicines (e.g. medicines used to relieve stomach cramps or spasms, or to treat Parkinson's disease or to prevent travel sickness).

Sandoz Rivastigmine should not be given together with metoclopramide (a medicine used to alleviate or prevent nausea and vomiting). There may be additive effects such as stiff limbs and trembling hands.

Your doctor will tell you if you can also take Sandoz Rivastigmine with your current medications. If you have to undergo surgery while taking Sandoz Rivastigmine, you should inform the doctor before you are given any anaesthetics (drugs that produce a loss of sensation).

Caution when Sandoz Rivastigmine is taken together with beta-blockers (medicines such as atenolol used to treat hypertension, angina, and other heart conditions). There may be additive effects such as bradycardia (slow heartbeat) that may result in syncope (fainting, loss of consciousness).

PROPER USE OF THIS MEDICATION

This medicine has been prescribed only for you. It must not be given to anybody else or used for any other illnesses.

Sandoz Rivastigmine should be taken with food.

Swallow the capsules whole with a drink, without opening or crushing them.

Usual dose:

You must take Sandoz Rivastigmine twice a day, once with your breakfast and once with your evening meal. Taking Sandoz

Rivastigmine at the same time each day will help you remember when to take your medicine.

Your doctor will tell you what dosage of Sandoz Rivastigmine to take, starting with a low dose and gradually increasing, depending on how you respond to the treatment. The highest dose that should be taken is 6 mg twice a day (12 mg/day).

To benefit from your medicine you must take it every day.

If you have questions about how long to take Sandoz Rivastigmine, talk to your doctor or your pharmacist.

Overdose:

If you have taken more medication than what has been prescribed, contact either a hospital emergency department, the nearest Poison Control Centre or your doctor immediately. You may require medical attention even if there are no symptoms.

- Some people who have accidentally taken too much oral Sandoz Rivastigmine have experienced nausea (feeling sick), vomiting (being sick), and diarrhea. You may become dehydrated (losing too much fluid) if vomiting or diarrhea are prolonged.
- Some people may also experience high blood pressure, hallucinations, slow heart beat and fainting

Missed Dose:

If you find you have forgotten to take your dose of Sandoz Rivastigmine, do not worry, wait and take the next dose at the usual time. Do NOT take two doses at once.

Do not stop taking Sandoz Rivastigmine or change your dose without talking with your doctor.

If you stop taking Sandoz Rivastigmine for more than three days, do NOT begin to take Sandoz Rivastigmine again without contacting your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, patients taking Sandoz Rivastigmine may experience side effects, although not everybody gets them.

In clinical studies most side effects of Sandoz Rivastigmine were of mild to moderate intensity.

The most common side effects (affect between 1 and 10 in every 100 patients) noted were:

- feeling sick (nausea), being sick (vomiting), diarrhea, stomach discomfort after meal, stomach pains and loss of appetite;
- dizziness, headache, sleepiness, drowsiness, trembling;
- agitation, confusion, nightmares, anxiety;
- weakness, fatigue, a general feeling of being unwell;
- sweating;
- weight loss.

Other common side effects reported Sandoz Rivastigmine are:

- muscle stiffness, difficulty in carrying out movements, uncontrollable movement of mouth, tongue and limbs, abnormally decreased muscular movement (worsening of Parkinson’s disease symptoms),
- irritation, reddening, rashes, itching (skin reactions),
- losing too much fluid (dehydration),
- restlessness,
- too much saliva,
- abnormal way of walking,
- light-headedness due to low blood pressure,
- high blood pressure.

These side effects will most probably disappear gradually as your body becomes used to the medicine or with a reduction in dose. If they persist, however, you should tell your doctor.

Uncommon side effects (affect between 1 and 10 in every 1,000 patients):

- difficulty in sleeping,
- change in blood test results related to liver function,
- accidental falls,
- abnormal posture with poor control of movements,
- inability to adequately retain urine (urinary incontinence).

Very rare side effects (affect less than 1 in 10,000 patients):

- blister.

Additional side effects reported with Sandoz Rivastigmine at an unknown frequency:

- aggression,
- alternating heart rhythms (heart disorders),
- skin inflammation, blisters or swelling of the skin that are increasing and spreading.

If you feel unwell in this or any other way or have any symptoms that you do not understand, or find distressing, you should contact your doctor immediately. Tell your doctor if any side effects become severe or troublesome to you. If you experience severe adverse events and cannot contact your doctor, stop taking the drug until you can discuss your symptoms with your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist right away		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Common	Crushing chest pain (heart attack)			√
	Losing too much fluid (dehydration)			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist right away		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Uncommon	Fainting		√	
	Depression		√	
	Loss of coordination, difficulty in speaking and signs of brain disorder (stroke)			√
Rare	Chest pain		√	
	Fits or convulsion (seizures)			√
	Rash, itching		√	
	Gastric (stomach) and duodenal (intestinal) ulcers		√	
Very rare	Blood in stools or when vomiting			√
	Severe vomiting that can lead to a rupture of the esophagus			√
	Urinary tract infection		√	
	Severe upper stomach pain, often with nausea and vomiting-(inflammation of the pancreas)			√
	Heart problems/ fast, slow or irregular heart beats			√
	Hallucinations		√	
	Blistering of the skin, mouth, eyes and genitals			√
Unknown	Yellow skin, yellowing of the whites of eyes, abnormal darkening of the urine or unexplained nausea, vomiting, tiredness and loss of appetite (liver disorders including hepatitis)			√
	Stiff limbs, trembling hands, body spasms, upward eye rolling, exaggeration of reflexes, drooling, difficulty moving how and when you want (extrapyramidal symptoms)			

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

HOW TO STORE IT

- Do not use Sandoz Rivastigmine after the expiry date.
- Store Sandoz Rivastigmine at room temperature (15 - 30°C).
- Keep Sandoz Rivastigmine in a safe place and 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 www.healthcanada.gc.ca/medeffect
- 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 0701E
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 www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

Please consult your doctor or pharmacist with any questions or concerns you may have regarding your individual condition.

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:
145 Jules-Léger
Boucherville (QC) Canada
J4B 7K8

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

This leaflet was prepared by Sandoz Canada Inc.

Last Revised: November 03, 2016.