

## **PATIENT MEDICATION INFORMATION**

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

#### **RIVASTIGMINE**

#### **Rivastigmine Hydrogen Tartrate Capsules**

Read this carefully before you start taking **RIVASTIGMINE** 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 **RIVASTIGMINE**.

#### **What is RIVASTIGMINE used for?**

RIVASTIGMINE is used in adults to treat symptoms of:

- mild to moderate Alzheimer's disease
- mild to moderate dementia happening at least 2 years after the diagnosis of Parkinson's disease

#### **How does RIVASTIGMINE work?**

People with Alzheimer's disease have low amounts of acetylcholine in the brain. It is a substance that is thought to be necessary for memory and other mental functions. RIVASTIGMINE helps stop the break down of acetylcholine. This helps increase the amount of acetylcholine in the brain. RIVASTIGMINE treats the symptoms and does not cure the disease.

#### **What are the ingredients in RIVASTIGMINE?**

Medicinal ingredient: rivastigmine (as rivastigmine hydrogen tartrate)

Non-medicinal ingredients: gelatin with red and/or yellow iron oxide, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, silicon dioxide and titanium dioxide.

#### **RIVASTIGMINE comes in the following dosage forms:**

**Capsules:** 1.5 mg, 3 mg, 4.5 mg or 6 mg of rivastigmine (as rivastigmine hydrogen tartrate).

#### **Do not use RIVASTIGMINE if:**

- you are allergic to rivastigmine (including rivastigmine patches) or to any of the other ingredients in this medicine
- you are allergic to a similar type of medicine
- you have severe liver problems
- you have had a previous allergic skin reaction with rivastigmine patches. The skin reaction:
  - spread beyond the patch size and/or was more severe at the patch site (such as blisters, increasing skin inflammation, swelling);
  - did not improve within 48 hours after removal of the patch

- you have had severe rash on large areas of your body or blistering of the skin, mouth, eyes, or genitals when taking rivastigmine (patch, capsules or oral solution)
- you have a history of heart problems including heart rhythm problems

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take RIVASTIGMINE. Talk about any health conditions or problems you may have, including if you:**

- have a condition that affects your heart and/or blood vessels (e.g., coronary artery disease, congestive heart failure)
- have fainting episodes
- have or had liver or kidney problems
- are taking any other medicines
- have or have a history of ulcers or bleeding in the stomach or intestines
- have an increased risk of developing ulcers (e.g. you are taking non-steroidal anti-inflammatory drugs (NSAIDs) or high doses of acetylsalicylic acid [ASA])
- have or had problems in passing urine
- have or have had seizures (such as epilepsy)
- have a respiratory disease that affects breathing (e.g., asthma or obstructive pulmonary disease)
- have a low body weight (less than 50 kg)
- are planning to have an operation with general anesthesia (medication that puts you to sleep)
- have uncontrolled involuntary movements of the body, face or limbs (extrapyramidal disorder)
- have an increased risk of developing serious and possibly life-threatening heart rhythm problems. Risk factors include if you:
  - have heart failure.
  - recently had a heart attack.
  - have a slower than usual heartbeat.
  - have been told by a healthcare professional that you have low potassium or magnesium levels in your blood.
  - have or have a family history of heart rhythm problems.
  - take medicines that are known to cause heart rhythm problems.
- are pregnant, think you might be pregnant or plan to become pregnant
- are breast feeding or planning to breast feed
- are older than 85 years of age.

**Other warnings you should know about:**

**RIVASTIGMINE can cause serious side effects, including:**

- **Gastro-intestinal problems:**
  - These include severe nausea, vomiting and diarrhea. You may become dehydrated if these problems happen for a long time. You may become dehydrated if they are not addressed. You or your caregiver should always monitor for these side effects during your treatment. Tell your healthcare professional if these side effects persist. Your dose may need to be changed.
  - Women are more at risk to experience these side effects than men.
  - RIVASTIGMINE can also cause increased acid secretion in the stomach. This can lead to bleeding in the gastrointestinal tract.
- **Extrapyramidal symptoms:** RIVASTIGMINE can make nervous system problems, like slow or uncontrollable of movements, trembling, seizures and changes in walking patterns worse. Your healthcare professional will monitor these conditions during RIVASTIGMINE treatment.
- **Stevens-Johnson Syndrome (SJS)** (severe skin rash): This rare serious and life-threatening skin reaction was reported in patients using RIVASTIGMINE. Stop taking RIVASTIGMINE and get medical help right away if you experience:
  - a severe rash or any other serious skin reaction such as blistering or peeling of the lips, eyes, mouth, nose or genitals.
  - fever, chills, headache, cough, body aches or swollen glands.
- **Heart rhythm problems:** RIVASTIGMINE may cause serious heart rhythm problems such as:
  - **QT Prolongation** (a heart rhythm condition where the heart muscle takes longer to contract and relax than usual).
  - **Torsade de pointes** (a life-threatening irregular heartbeat) in patients with risk factors.
- **Pancreatitis** (inflammation of the pancreas): It can occur shortly after starting treatment or even after several months or years of treatment with RIVASTIGMINE.

See the “**Serious side effects and what to do about them**” table, below, for more information on these and other serious side effects.

**Driving vehicles and using machines:** RIVASTIGMINE may cause you to feel dizzy or drowsy. If you feel dizzy or drowsy, do not drive, use machines or perform any other tasks that require your attention. Your healthcare professional will tell you if you can drive or use machines.

**Pregnancy:** It is not known if RIVASTIGMINE can harm an unborn baby. Therefore, you should not use it if you can become pregnant unless your healthcare professional has determined the potential benefits outweigh the potential risks to your baby. If you discover that you are pregnant during your treatment with RIVASTIGMINE, tell your healthcare professional right away.

**Breastfeeding:** It is not known if RIVASTIGMINE can pass into breast milk and harm a breastfed baby. Therefore, RIVASTIGMINE is not recommended during breastfeeding. Talk to your

healthcare professional about other ways to feed your baby during your treatment with RIVASTIGMINE.

**Surgery:** Tell any doctor, dentist, pharmacist, or healthcare professional that you see, that you are taking this medicine. RIVASTIGMINE may exaggerate the effects of some muscle relaxants used during anesthesia.

**Check-ups and testing:**

- Alzheimer’s disease and cholinesterase inhibitors, such as RIVASTIGMINE, may cause a low appetite and/or significant weight loss. Your healthcare professional will closely monitor your appetite and weight during your treatment with RIVASTIGMINE.
- Your healthcare professional may also monitor your heart rate during this time.

**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 RIVASTIGMINE:**

- Other cholinesterase inhibitors or cholinomimetic medicines (used to treat symptoms of Alzheimer’s disease, dementia, myasthenia gravis, glaucoma and urinary problems). Examples include bethanechol.
- Anticholinergic medicines (used to treat various conditions such as asthma, chronic obstructive pulmonary disease (COPD), bladder problems, gastrointestinal disorders, and symptoms of Parkinson’s disease), Examples include oxybutynin and tolterodine.
- Medicines used to treat nausea and vomiting such as metoclopramide
- Medicines used to treat high blood pressure and chest pain, such as atenolol (beta-blockers)
- Medicines used to prevent pain during surgery
- Medicines that are known to lengthen a part of the heartbeat called “QT interval”. These can include:
  - Medicines that can affect your heart rhythm or the electrical system of your heart such as quinidine, amiodarone, sotalol
  - Medicines used to treat depression like citalopram, escitalopram, amitriptyline
  - Medicines used to treat mental disorders like phenothiazine derivatives, sertindole, pimozide, ziprasidone
  - Medicines used to treat stomach problems like cisapride
  - Medicines used to treat allergies like mizolastin
  - Medicines used to treat bacterial infections such as clarithromycin, erythromycin, levofloxacin, moxifloxacin
  - Medicines used to treat malaria such as halofrantrine
- Medicines used to prevent and control seizures
- Nicotine or tobacco products

**How to take RIVASTIGMINE:**

- Take exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

- Take RIVASTIGMINE with food. Take RIVASTIGMINE twice a day, once with your breakfast and once with your evening meal.
- Taking RIVASTIGMINE at the same time each day will help you remember when to take your medicine.
- Swallow the capsules whole with a drink. Do not open or crush the capsules.

**Usual adult dose:**

- Your healthcare professional will tell you how much RIVASTIGMINE to take.
- The maximum dose is 6 mg twice a day (12 mg/day).

Your healthcare professional may lower your dose, stop your treatment for a period of time or recommend that you stop treatment completely. This may happen if you:

- experience serious side effects, or
- your disease gets worse.

**Overdose:**

- Symptoms of taking too much RIVASTIGMINE can include:
  - nausea, vomiting, or diarrhea. This can lead to dehydration.
  - high or low blood pressure, slow heart beat, slower breaths, muscle weakness
  - headache, dizziness, hallucinations, confusion, fainting, sleepiness
  - stomach pain, shaking, sweating

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

**Missed Dose:**

- If you miss a dose of RIVASTIGMINE, take the next dose at the usual time. Do not take two doses at once.
- Do not stop taking RIVASTIGMINE or change your dose without talking with your healthcare professional.
- Your healthcare professional will tell you your new dose if you stop taking RIVASTIGMINE for more than three days.

**What are possible side effects from using RIVASTIGMINE?**

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

- nausea, vomiting
- loss of appetite, weight loss
- dizziness, headache
- accidental falls
- diarrhea, constipation, stomach discomfort after meals, stomach pains, heartburn
- inability to adequately retain urine (urinary incontinence)

- difficulty in sleeping, tiredness, weakness
- agitation, confusion, nightmares, restlessness, anxiety, aggression
- excessive sweating
- a general feeling of being unwell
- fever, stuffy or runny nose
- joint pain, muscle pain or spasms, muscle stiffness
- shortness of breath
- high blood pressure, light-headedness due to low blood pressure
- ringing in the ears
- blurry vision
- trembling
- too much saliva

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>COMMON</b>			
<b>Anemia</b> (decreased number of red blood cells): fatigue, loss of energy, looking pale, weakness, shortness of breath		√	
<b>Severe nausea, vomiting and/or diarrhea, dehydration:</b> thirst, headache, general discomfort, loss of appetite, decrease urine, confusion, unexplained tiredness			√
<b>Urinary tract infection:</b> pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine		√	
<b>UNCOMMON</b>			
<b>Depression</b> (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive) and thoughts of death or		√	

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	
suicide.			
<b>Fainting</b>		√	
<b>Heart rhythm problems:</b> irregular or fast or slow heartbeat, shortness of breath, dizziness, fainting			√
<b>Myocardial infarction</b> (heart attack): pressure or squeezing pain in the chest, jaw, left arm, between the shoulder blades or upper abdomen, shortness of breath, dizziness, fatigue, light headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat			√
<b>Seizures:</b> fits or convulsions			√
<b>Severe confusion</b>			√
<b>Stomach ulcer and gastrointestinal bleeding:</b> blood in the stools, black, tarry stools or vomiting blood			√
<b>Stroke:</b> sudden numbness or weakness of your arm, leg or face, especially if only on one side of the body; sudden confusion, difficulty speaking or understanding others; sudden difficulty in walking or loss of balance or coordination; suddenly feeling dizzy or sudden severe headache with no known cause			√
<b>RARE</b>			
<b>Chest pain</b>		√	
<b>VERY RARE</b>			
<b>Hallucinations:</b> seeing, feeling or hearing things that are not there			√
<b>Liver disorder:</b> yellowing of skin and the whites of eyes, darkening			√

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	
of the urine, unexplained nausea, vomiting, loss of appetite, itching, upper stomach pain, tiredness			
<b>Pancreatitis</b> (inflammation of the pancreas): upper abdominal pain, fever, rapid heartbeat, nausea, vomiting, tenderness when touching the abdomen			√
<b>Stevens-Johnson Syndrome (SJS)</b> (severe skin rash): redness, blistering and/or 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			√
<b>UNKNOWN</b>			
<b>Extrapyramidal symptoms:</b> problems controlling movements of the body or limbs, including, but not limited to, stiff limbs, trembling hands, body spasms, upward eye rolling, exaggeration of reflexes, drooling, difficulty moving how and when you want			√

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:**

- Keep RIVASTIGMINE in a safe place and out of the reach and sight of children.
- Store RIVASTIGMINE capsules between 15°C - 30°C.

**If you want more information about RIVASTIGMINE:**

- 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>); 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)

This leaflet was prepared by Pro Doc Ltée.

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