

PART III: CONSUMER INFORMATION

PrEXELON®

Rivastigmine Hydrogen Tartrate Capsules and Oral Solution

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

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

ABOUT THIS MEDICATION

What the medication is used for:

EXELON® 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. EXELON® works by inhibiting an enzyme (acetylcholinesterase) which breaks down acetylcholine. This in turn increases the amount of acetylcholine in the brain. EXELON® is a treatment of symptoms, not a cure of the disease.

In clinical studies with EXELON®, 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, EXELON® 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 EXELON®

- If you know that you are allergic (hypersensitive) to rivastigmine (including EXELON® 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 EXELON® 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 EXELON® PATCH, EXELON® capsules or oral solution.

EXELON® should only be used if prescribed to you by your doctor.

What the medicinal ingredient is:

EXELON® contains the active substance rivastigmine hydrogen tartrate.

What the nonmedicinal ingredients are:

EXELON® 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.

EXELON® oral solution contains sodium benzoate, citric acid, sodium citrate, quinoline yellow WS dye E104 and purified water.

EXELON® oral solution should be manipulated with caution as benzoic acid is a mild irritant to the skin, eyes, and mucous membranes.

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.

Oral solution: Each mL of oral solution contains 2 mg of rivastigmine as rivastigmine hydrogen tartrate.

WARNINGS AND PRECAUTIONS

BEFORE you use EXELON® talk to your doctor or 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 EXELON® 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.

EXELON® 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).

EXELON® 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 EXELON® with your current medications. If you have to undergo surgery while taking EXELON®, you should inform the doctor before you are given any anaesthetics (drugs that produce a loss of sensation).

Caution when EXELON® 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.

EXELON® should be taken with food.

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

Oral solution: Remove the oral dosing syringe provided from its protective case. Using the syringe, withdraw the prescribed amount of EXELON® oral solution from the container. Each dose of EXELON® oral solution may be swallowed directly from the syringe or first mixed with a small glass of water, cold fruit juice or soda. Stir and drink the entire mixture.

1. Remove oral dosing syringe from its protective case. Push down and twist child resistant closure to open bottle.



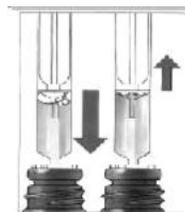
2. Insert tip of syringe into opening of white stopper.



3. While holding the syringe, pull the plunger tip to the level (see markings on side of syringe) that equals the dose prescribed by your doctor.



4. Before removing syringe containing prescribed dose from bottle, push out large bubbles by moving plunger up and down a few times. After the large bubbles are gone, pull the plunger again to the level that equals the dose prescribed by your doctor. Do not worry about a few tiny bubbles. This will not affect your dose in any way. Remove the syringe from the bottle.



5. You may swallow EXELON® Oral Solution directly from the syringe or mix with a small glass of water, cold fruit juice or

soda; be sure to stir completely and to drink the entire mixture right away. **DO NOT MIX WITH OTHER LIQUIDS**



6. After use, wipe outside of syringe with a clean tissue and put it back in its case. Close bottle using child resistant closure.



Usual dose:

You must take EXELON® twice a day, once with your breakfast and once with your evening meal. Taking EXELON® at the same time each day will help you remember when to take your medicine.

Your doctor will tell you what dosage of EXELON® 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 EXELON®, 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 EXELON® 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 EXELON®, do not worry, wait and take the next dose at the usual time. Do NOT take two doses at once.

Do not stop taking EXELON® or change your dose without talking with your doctor.

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

In clinical studies most side effects of EXELON® 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 with EXELON® 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 EXELON® 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)			√
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,			√

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	
	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)			√

Additional side effects which have been reported with EXELON® PATCH that are not listed above for EXELON® capsules or oral solution include:

Uncommon: hyperactivity (unusual high level of activity, restlessness).

Very rare: liver failure (nausea, vomiting, loss of appetite, itching, upper stomach pain)

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

HOW TO STORE IT

- Do not use EXELON® after the expiry date.
- Store EXELON® at room temperature (15 - 30°C). Do not refrigerate or freeze EXELON® oral solution.
- Store EXELON® Oral Solution in the original package in an upright position.
- Keep EXELON® 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 found at:

<http://www.novartis.ca>

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at:

1-800-363-8883

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