

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

Pr DONEPEZIL

Donepezil Hydrochloride Tablets, House Standard

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

ABOUT THIS MEDICATION

What the medication is used for:

This medicine is called DONEPEZIL (which contains donepezil hydrochloride).

Donepezil hydrochloride is one of a group of drugs called "cholinesterase inhibitors".

DONEPEZIL is used for the symptomatic treatment of mild, moderate, and severe Alzheimer's disease.

DONEPEZIL can only be obtained with a prescription from a doctor.

What it does:

In the brains of persons with Alzheimer's disease, there is a decrease in the function of a neurotransmitter system which uses acetylcholine as its chemical messenger. DONEPEZIL acts by inhibiting an enzyme called acetylcholinesterase, leading to an increase in the level of acetylcholine in the brain, which may help relieve the symptoms of Alzheimer's disease.

In clinical studies, patients treated with donepezil hydrochloride showed improvement, remained unchanged, or declined more slowly as compared to patients who received a placebo (sugar tablet). Benefits were seen in memory and other mental functions, as well as in the ability to perform daily activities. DONEPEZIL 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 you are allergic to this medicine, any of its inactive ingredients (see the section "What the important nonmedicinal ingredients are"), or to piperidine derivatives such as rifabutin, methylphenidate, biperiden HCl, trihexyphenidyl, bupivacaine, and paroxetine HCl.

What the medicinal ingredient is:

Donepezil hydrochloride.

What the non medicinal ingredients are:

Hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose. The coating contains: hypromellose, polyethylene glycol and titanium dioxide. Additionally, the 10-mg tablet contains iron oxide yellow as a coloring agent.

What dosage forms it comes in:

Tablets: 5 mg and 10 mg

WARNINGS AND PRECAUTIONS

Tell your doctor if you have any muscle pain, tenderness, soreness or weakness, especially if you also have a fever, during treatment with DONEPEZIL.

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

	Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Rare	Rhabdomyolysis: combination of muscle pain, tenderness, or weakness, or joint pain accompanied by a fever or very dark urine that you cannot explain		✓	
Very Rare	Neuroleptic Malignant Syndrome: A state of high fever, muscle stiffness, irregular blood pressure, pulse and or heartbeats, altered consciousness			✓

BEFORE you use DONEPEZIL talk to your doctor or pharmacist if:

- You are taking other medicines, including prescription drugs or products that you can buy without a prescription, such as herbal (natural) products.
- You have a condition affecting your heart,

kidney, liver or your lungs, such as asthma or obstructive pulmonary disease.

- You have had seizures.
- You have had fainting spells.
- You have a history of peptic ulcers or have an increased risk of developing ulcers (for example, if you are taking non-steroidal anti-inflammatory drugs [NSAIDS] or high doses of acetylsalicylic acid [ASA]).
- If you are pregnant or breastfeeding.
- An operation with a general anesthetic is needed, inform your doctor about the use DONEPEZIL.

PROPER USE OF THIS MEDICATION

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

- In order to obtain the best results from DONEPEZIL, it must be taken every day, exactly as prescribed by your doctor. Never change the dose yourself.
- Take DONEPEZIL once daily, at the same time every day, in the morning or evening.
- Take DONEPEZIL with or without food.
- DONEPEZIL tablets should be swallowed whole with water.

A Reminder: This medicine has been prescribed only for you or for the person you are caring for. Never give it to anyone else.

Overdose:

If you think you have taken too much DONEPEZIL, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss taking a dose of DONEPEZIL do not worry, just take the next dose when it is due. Do NOT take 2 doses at once.

If you have problems remembering to take medications, it may be necessary to have someone help you.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its beneficial effect, DONEPEZIL may cause some undesirable reactions. The most common side effects include nausea (feeling sick) and diarrhea. In clinical studies, these effects were often mild, and generally went away with continued treatment. If they persist you should tell your doctor.

Other possible side effects include:

- insomnia (difficulty sleeping)
- vomiting (being sick)
- muscle cramps
- fatigue
- anorexia (loss of appetite)
- fainting

If you feel unwell in any other way or have any symptoms that you do not understand, or find distressing, you should contact your doctor immediately. If you experience severe adverse events, stop taking the drug until you can discuss your symptoms with your doctor.

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

HOW TO STORE IT

Store between 15°C and 30°C. Protect from moisture.

Keep this medicine in a safe place, out of reach and sight of children.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](http://www.healthcanada.gc.ca/medeffect)
(www.healthcanada.gc.ca/medeffect);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal
Locator 0701E
Ottawa, ON
K1A 0K9Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](http://www.healthcanada.gc.ca/medeffect)
(www.healthcanada.gc.ca/medeffect).

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 Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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