

## PART III: CONSUMER INFORMATION

### <sup>Pr</sup>DONEPEZIL

#### Donepezil Hydrochloride Tablets, USP

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 nonmedicinal ingredients are"), or to piperidine derivatives such as Mycobutin (rifabutin), Ritalin (methylphenidate), Akineton (biperiden HCl), trihexyphenidyl, bupivacaine, and Paxil (paroxetine HCl).

##### What the medicinal ingredient is:

DONEPEZIL contains donepezil hydrochloride.

What the non-medicinal ingredients are: Lactose monohydrate, low substituted hydroxypropyl cellulose, maize starch, microcrystalline cellulose, magnesium stearate, hypromellose, polyethylene glycol, titanium dioxide and talc. Additionally, the 10 mg tablet contains iron oxide yellow, as a colouring agent.

##### What dosage forms it comes in:

DONEPEZIL is available as tablets. The 5 mg tablets are white and the 10 mg tablets are yellow.

#### 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.

##### **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] [Aspirin®]).
- 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 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, or a person you are caring for, have taken too much DONEPEZIL, contact a 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.

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

Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate help
		Only if severe	In all cases	
Rare	<b>Rhabdomyolysis:</b> combination of muscle pain, tenderness, or weakness, or joint pain accompanied by a fever or very dark urine that you cannot explain		X	
Very Rare	<b>Neuroleptic Malignant Syndrome:</b> A state of high fever, muscle stiffness, irregular blood pressure, pulse and or heartbeats, altered consciousness			X

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

*pharmacist.*

**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.*

**HOW TO STORE IT**

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

Keep DONEPEZIL at controlled room temperature, 15°C to 30°C and away from moisture.

**MORE INFORMATION**

If you want more information about DONEPEZIL:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer 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 calling the sponsor Sivem Pharmaceuticals ULC at 1-855-788-3153.

Or at [www.sivem.ca](http://www.sivem.ca)

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