

PART III: CONSUMER INFORMATION**ARICEPT®/ARICEPT® RDT
(donepezil hydrochloride)**

This leaflet is part III of a three-part "Product Monograph" published when ARICEPT was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ARICEPT/ARICEPT RDT. 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 **ARICEPT/ARICEPT RDT** (which contains donepezil hydrochloride).

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

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

ARICEPT/ARICEPT RDT 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. **ARICEPT/ARICEPT RDT** 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 **ARICEPT/ARICEPT RDT** 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. **ARICEPT/ARICEPT RDT** 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 Mycobutin (rifabutin), Ritalin (methylphenidate), Akineton (biperiden HCl), trihexyphenidyl, bupivacaine, and Paxil (paroxetine HCl).

What the medicinal ingredient is:

ARICEPT/ARICEPT RDT contain donepezil hydrochloride.

What the important nonmedicinal ingredients are:

ARICEPT tablets: Lactose monohydrate. Other non-medicinal ingredients include corn starch, microcrystalline cellulose, hydroxypropylcellulose, magnesium stearate, talc, polyethylene glycol, hypromellose, and titanium dioxide. The 10 mg tablets also contain yellow iron oxide.

ARICEPT RDT: No known important non-medicinal ingredient. Other non-medicinal ingredients include mannitol, silica colloidal anhydrous, κ-carrageenan, and polyvinyl alcohol. The 10 mg rapidly disintegrating tablets also contain yellow iron oxide.

What dosage forms it comes in:

ARICEPT is available as tablets and **ARICEPT RDT** is available as rapidly disintegrating tablets. The 5 mg tablets are white and the 10 mg tablets are yellow for both **ARICEPT** and **ARICEPT RDT**.

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 **ARICEPT/ARICEPT RDT**.

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		X	
Very Rare	Neuroleptic Malignant Syndrome: A state of high fever, muscle stiffness, irregular blood pressure, pulse and or heartbeats, altered consciousness			X

BEFORE you use ARICEPT/ARICEPT RDT 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 **ARICEPT/ARICEPT RDT**.

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 **ARICEPT/ARICEPT RDT**, it must be taken every day, exactly as prescribed by your doctor. Never change the dose yourself.
- Take **ARICEPT/ARICEPT RDT** once daily, at the same time every day, in the morning or evening.
- Take **ARICEPT/ARICEPT RDT** with or without food. **ARICEPT tablets** should be swallowed whole with water.

ARICEPT RDT should be placed on the tongue and allowed to disintegrate before swallowing 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 more medication has been taken than what has been prescribed, contact either your doctor, hospital emergency department or the nearest poison control center immediately.

Missed Dose:

If you miss taking a dose of **ARICEPT/ARICEPT RDT** 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, **ARICEPT/ARICEPT RDT** 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 ARICEPT/ARICEPT RDT, contact your doctor or pharmacist.

HOW TO STORE IT

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

Keep **ARICEPT** tablets and **ARICEPT RDT** in a cool dry place (15 to 30°C) and avoid exposure to moisture.

ARICEPT RDT is also sensitive to light and should not be removed from blisters until immediately prior to administration.

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, Ontario
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

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.pfizer.ca> or by contacting the sponsor, Pfizer Canada Inc.

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