

## **PATIENT MEDICATION INFORMATION**

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

#### **ARICEPT®**

#### **donepezil hydrochloride tablets**

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

#### **What is ARICEPT used for?**

ARICEPT is used in adults to treat the symptoms of mild, moderate and severe dementia due to Alzheimer's disease.

#### **How does ARICEPT work?**

People with Alzheimer's disease have a low amount of a chemical called acetylcholine in their brain. It is a substance that is thought to be necessary for memory and other mental functions. ARICEPT helps to stop the breakdown of acetylcholine, which helps to increase the amount of acetylcholine in the brain. This may help relieve the symptoms of dementia related to Alzheimer's disease. It is important to remember that ARICEPT treats the symptoms, it does not cure the disease.

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

Medicinal ingredient: donepezil hydrochloride

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

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

Tablets: 5 mg, 10 mg.

#### **Do not use ARICEPT if:**

- you are allergic to donepezil hydrochloride, or to any of the other ingredients in ARICEPT (see the section "What are the ingredients in ARICEPT?")
- you are allergic to piperidine derivatives such as rifabutin, methylphenidate, biperiden hydrochloride, trihexyphenidyl, bupivacaine, or paroxetine hydrochloride.
- 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 ARICEPT. Talk about any health conditions or problems you may have, including if you:**

- have a condition called ‘sick sinus syndrome’ or other heart rhythm disorders.
- have a condition that affects your heart and/or blood vessels such as coronary artery disease, congestive heart failure or a recent heart attack.
- have a history of muscle disorders, including any involuntary movements of the body, face, or limbs.
- have or have had any liver or kidney problems.
- have a condition that affects your lungs, such as asthma or obstructive pulmonary disease.
- have had seizures.
- have had fainting spells.
- 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, commonly known as Aspirin®).
- need an operation with a general anesthetic; tell your healthcare professional you are taking ARICEPT.
- have hypothyroidism (low levels of thyroid hormone), but are not receiving treatment for it.
- have any of the following rare hereditary problems, because ARICEPT contains lactose:
  - galactose intolerance.
  - Lapp lactase deficiency.
  - glucose-galactose malabsorption.
- are pregnant, think you might be pregnant, or plan to become pregnant.
- are breastfeeding, or plan to breastfeed.
- are elderly (85 years of age or older) and have a low body weight.

**Other warnings you should know about:**

**Muscle problems:** If you experience any muscle pain, tenderness, or weakness and darkened urine, accompanied by a fever or a feeling of being unwell, tell your healthcare professional **right away**.

**Driving and using machines:** ARICEPT may cause you to feel dizzy or drowsy, especially when you first start taking it, or change your dose. 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.

**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 ARICEPT:**

- other medicines like ARICEPT, used to treat symptoms of Alzheimer’s disease.
- medicines known as ‘anticholinergics’ (used to stop the action of a chemical in the brain called acetylcholine).
- medicines known as ‘neuromuscular blocking agents’, such as succinylcholine (used as a muscle relaxant).
- medicines known as ‘cholinergic agonists’, such as bethanechol (used to stimulate the bladder).

- medicines used to treat heart rhythm disorders, such as quinidine, amiodarone, sotalol.
- medicines used to treat depression, such as citalopram, escitalopram, amitriptyline.
- medicines used to treat psychosis, such as phenothiazine, sertindole, pimozide, ziprasidone.
- certain antibiotics, such as clarithromycin, erythromycin, levofloxacin, moxifloxacin, rifampin.
- ketoconazole, used to treat fungal infections.
- medicines used to treat seizure disorders, such as phenytoin, carbamazepine, phenobarbital.
- dexamethasone, used to treat inflammation.
- metoclopramide, used to treat stomach and esophageal problems.
- medicines known as ‘beta-blockers’, used to treat abnormal heart rhythms.

**How to take ARICEPT:**

- Take ARICEPT exactly as your healthcare professional tells you to.
- Swallow tablets whole, with water.
- ARICEPT can be taken with or without food.
- Taking ARICEPT at the same time each day will help you remember when to take your medicine.
- If you experience sleep disturbances such as abnormal dreams, nightmares or insomnia, tell your healthcare professional. They may advise you to take ARICEPT in the morning.

**Usual Dose:**

The recommended starting dose is 5 mg once daily in the morning or evening. Depending on your response to ARICEPT, your healthcare professional may increase your dose. The maximum recommended dose is 10 mg once daily.

**Overdose:**

If you think you, or a person you are caring for, have taken too much ARICEPT, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada’s toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no symptoms.

**Missed Dose:**

If you miss taking a dose of ARICEPT, skip the missed dose and take the next dose at the regular scheduled time. If you have missed your dose for several days or more, tell your healthcare professional, they will tell you how to restart your treatment.

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

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

Side effects may include:

- insomnia (difficulty sleeping)
- abnormal dreams
- vomiting (being sick)
- nausea
- diarrhea
- muscle cramps
- fatigue
- anorexia (loss of appetite)
- weight loss
- fever
- headache
- dizziness
- body pain
- accidental falls
- bruising, cuts
- frequent urination
- urinary tract infection (UTI)
- aggression
- restlessness
- hallucinations
- 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>UNCOMMON</b>			
<b>Anemia</b> (decreased number of red blood cells): fatigue, loss of energy, looking pale, weakness, shortness of breath		√	
<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		√	

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	
drive) and thoughts of death or suicide			
Fainting		√	
<b>Heart Problems</b> (problems affecting your heart muscle, valves or rhythm): chest pain or discomfort, high blood pressure, irregular, fast or slow heart rhythm, shortness of breath, dizziness, fainting			√
<b>Seizures</b> (fits or convulsions)			√
<b>Stomach ulcer and gastrointestinal bleeding:</b> blood in the stools, black, tarry stools or vomiting blood			√
<b>RARE</b>			
<b>Rhabdomyolysis</b> (breakdown of damaged muscle): combination of muscle pain, tenderness, or weakness, or joint pain accompanied by a fever or very dark urine that you cannot explain		√	
<b>VERY RARE</b>			
<b>Neuroleptic Malignant Syndrome:</b> high fever, pronounced muscle stiffness or inflexibility, rapid or irregular heartbeat, sweating, state of confusion or reduced consciousness			√
<b>FREQUENCY 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			√
Libido increased, hypersexuality		√	
<b>Liver disorder:</b> yellowing of skin and the whites of eyes, darkening of the urine, unexplained nausea,			√

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	
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>Pisa Syndrome</b> (a neurological condition): involuntary muscle contraction with abnormal bending of the body and head to one side		√	

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

Keep out of reach and sight of children.

#### If you want more information about ARICEPT:

- 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>); the manufacturer's website [www.pfizer.ca](http://www.pfizer.ca), or by calling 1-800-463-6001

(Medical Information)

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