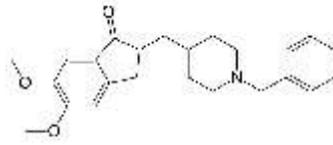


Rx DONEPEZIL

(Donepezil is an oral medication used to treat Alzheimer's disease.)



DRUG CLASS AND MECHANISM

Donepezil is an oral medication used to treat Alzheimer's disease. It belongs to a class of drugs called cholinesterase inhibitors that also includes tacrine (Cognex). Scientists believe that Alzheimer's disease may result from a deficiency in chemicals (neurotransmitters) used by nerves in the brain to communicate with one another. Donepezil inhibits acetylcholinesterase, an enzyme responsible for the destruction of one neurotransmitter, acetylcholine. This leads to increased concentrations of acetylcholine in the brain, and the increased concentrations are believed to be responsible for the improvement seen during treatment with donepezil. Donepezil improves the symptoms but does not slow down the progression of Alzheimer's disease. Donepezil was approved by the FDA in 1996.

PRESCRIPTION: yes

GENERIC AVAILABLE: yes

PREPARATIONS

Aricept is available in 5 and 10 mg tablets. Aricept ODT (orally disintegrating tablets) also are available in 5 and 10 mg tablets.

PRESCRIBED FOR

Donepezil is used for the treatment of mild to moderate dementia of the Alzheimer's type.

DOSING

Donepezil is generally taken once daily at night prior to retiring. Its absorption is not affected by food so that it may be taken with or without food.

DRUG INTERACTIONS

Drugs with anti-cholinergic properties that can cross into the brain, such as atropine, benzotropine (Cogentin), and trihexyphenidyl (Artane) counteract the effects of donepezil and should be avoided during therapy with donepezil.

Donepezil is metabolized (eliminated) by enzymes in the liver. The rate of metabolism of donepezil may be increased by medications that increase the amounts of these enzymes, such as carbamazepine (Tegretol), dexamethasone (Decadron), phenobarbital, phenytoin (Dilantin), and rifampin (Rifadin). By increasing elimination, these drugs may reduce the effects of donepezil.

Ketoconazole (Nizoral) has been shown to block the enzymes in the liver that metabolize donepezil. Therefore, concurrent use of ketoconazole and donepezil may result in increased concentrations of donepezil in the body and possibly lead to donepezil side effects. Quinidine (Quinidex, Quinaglute) also has been shown to inhibit the enzymes that metabolize donepezil and may cause donepezil side effects.

USES

Donepezil is used to treat mild to moderate confusion (dementia) related to Alzheimer's disease. It does not cure Alzheimer's disease, but it may improve memory, awareness, and the ability to function. This medication is an enzyme blocker that works by restoring the balance of natural substances (neurotransmitters) in the brain.

HOW TO USE

Take this medication by mouth once daily with or without food, usually just before bedtime, or as directed by your doctor. If you experience sleep problems (insomnia), talk to your doctor about switching to a morning dose. Use this medication regularly in order to get the most benefit from it. Do not stop taking it or increase the dosage unless your doctor instructs you to do so. It may take a few weeks before the full benefit of this drug takes effect. Inform your doctor if your condition worsens.

SIDE EFFECTS

Nausea, vomiting, diarrhea, loss of appetite, tiredness, drowsiness, trouble sleeping, or muscle cramps may occur as your body adjusts to the drug. These effects usually last 1-3 weeks and then subside. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: mental/mood changes (depression), slow/irregular heartbeat, fainting, vision problems, more frequent urination/trouble urinating, weight loss. Tell your doctor immediately if any of these rare but very serious side effects occur: black stools, vomit that looks like coffee grounds, severe stomach/abdominal pain, seizures. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS

Before taking donepezil, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: breathing problems (e.g., asthma, chronic obstructive pulmonary disease), heart disease (heart

conduction disorders), seizures, stomach/intestinal disease (e.g., ulcers, bleeding), trouble urinating (e.g., enlarged prostate). This drug may make you drowsy or cause vision problems. Do not drive, use machinery, or do any activity that requires alertness or clear vision until you are sure you can perform such activities safely. Limit alcoholic beverages. Before having surgery, tell your doctor or dentist that you are taking this medication. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known whether this drug passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS

Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop or change the dosage of any medicine before checking with them first. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: anticholinergic medications (e.g., benztropine, diphenhydramine), aspirin (high doses used for arthritis), cholinergic drugs (e.g., bethanechol), cholinesterase inhibitors (e.g., neostigmine), long-term use of non-steroidal anti-inflammatory drugs (NSAIDs, such as ibuprofen, naproxen), drugs affecting the liver enzymes that remove donepezil from your body (such as carbamazepine, dexamethasone, phenobarbital, phenytoin, rifampin). Check all prescription and nonprescription medicine labels carefully since many medications contain pain relievers/fever reducers (NSAIDs such as aspirin, ibuprofen, or naproxen) that if taken together with donepezil, may increase your risk for stomach/intestinal bleeding. Low-dose aspirin, as prescribed by your doctor for specific medical reasons such as heart attack or stroke prevention (usually at dosages of 81-325 milligrams per day), should be continued. Consult your doctor or pharmacist for more details. This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include severe or persistent nausea/vomiting, excessive sweating, very slow heartbeat, slow or shallow breathing, seizures.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product. **MEDICAL ALERT:** Your condition can cause complications in a medical emergency. For enrollment information call MedicAlert at 1-800-854-1166 (USA) or 1-800-668-1507 (Canada).

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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