

DRUG FACTS BOX

Aricept (donepezil)

ARICEPT tablets for mild-to-moderate dementia from Alzheimer's Disease

What is the purpose of this box?

To explain the benefits and side effects of ARICEPT 5 mg and 10 mg to help you decide whether to use this drug.

What is this drug for?

To treat symptoms of dementia or mental decline due to mild-to-moderate Alzheimer's disease, which impairs people's ability to remember, learn, and reason. Like other dementia drugs, ARICEPT may temporarily improve symptoms, but it is not a cure.

Who might consider taking it?

Adults with mild-to-moderate Alzheimer's Disease as indicated by a score of between 10 and 20 out of a possible 30 on the mini-mental status test of basic thinking skills (MMSE). An interactive version of the test is available at <http://tinyurl.com/maghexp>.

Precautions to take

Patients and caregivers need to ensure adequate fluid intake because the drug can cause **dehydration** from not eating, or prolonged **vomiting** or **diarrhea**. Be alert for weight loss, bleeding in the stomach and intestines, worsening of symptoms of asthma or obstructive lung disease and fainting from a slow heart rate. Routinely evaluate the ability to continue driving or operating machinery. **ARICEPT CAN ALSO CAUSE OTHER UNCOMMON, LIFE-THREATENING OR SERIOUS SIDE EFFECTS: A very slow heart rate**, even in people with no prior heart problems, which could be potentially dangerous; **fainting** from too slow heart rate has been reported; **blockage** in the bladder making it difficult or impossible to urinate; **seizures**; **bleeding** in the stomach or intestines, especially people who have a history of ulcers or who are taking nonsteroidal anti-inflammatory drugs (NSAIDs) such as aspirin, ibuprofen (Advil, Motrin, and generic), or naproxen (Aleve and generic).

What other choices are there?

Galatamine (RAZADYNE tablets, RAZADYNE extended release capsules and generic) and rivastigimine (EXELON patch, EXELON capsules, and generic capsules). Monitored exercise therapy, occupational therapy, and activities that stimulate the brain such as art and music may also be helpful.

BOTTOM LINE

■ ARICEPT's benefit

Limited benefit in slowing deterioration of remembering, learning and reasoning—Studies have consistently shown that, for the typical patient, Aricept slows deterioration in remembering, learning and reasoning by **only a modest amount**. The results reported in this Drug Facts Box™ are essentially the same as those reported in recent high-quality systematic reviews of all trials testing the drug for dementia. [Cochrane Collaboration (2012), UK Health Technology Assessment Programme (2012), American College of Physicians (2008) and Drug Effectiveness Review Project (2006)]

Never shown to improve quality of life, independent function or reduce institutionalization—No evidence that ARICEPT improves quality of life for either patients or caregivers, prolongs people's ability to function independently, or reduces the need for institutionalization—all major goals of treating dementia. Here's how the FDA's Medical Reviewer described the benefit of Aricept [Overall Conclusion in the Executive Summary]

"Patients receiving [ARICEPT] have a statistically significant mean improvement in cognitive performance ...and have a statistically significant mean clinical improvement as demonstrated on the [overall rating]. As seen with tacrine, another cholinesterase inhibitor, the size of the effect is modest. The drug does not appear to have an effect on the underlying progression of the disease...suggested by the loss of cognitive function 3 to 6 week after discontinuing ARICEPT to a level seen in patients who were treated with PLACEBO. [The company] was unable to demonstrate a consistent effect in measures claiming to evaluate quality of life".

■ ARICEPT's harm

Can cause bothersome and potentially serious side effects—ARICEPT can cause fainting, slow heart rate, diarrhea, nausea, vomiting and decreased appetite—all of which can be serious for older people with dementia. Nausea, vomiting and diarrhea are less common with 5-mg than 10-mg dose.

Long track record means new, unexpected side effects are unlikely—The FDA approved ARICEPT 5 mg and 10 mg for mild to moderate dementia from Alzheimer's disease in 1996. Because large numbers of Alzheimer's patients have taken this drug for many years, new important side effects are unlikely to emerge.

■ Comparing doses

The FDA approved doses of 5 mg to 10 mg daily. The 5-mg dose may be the better choice since it works about as well as the 10-mg dose with substantially fewer side effects. To reduce the chance of side effects, patients should take 5 mg daily for 4 to 6 weeks before increasing to a higher dose.

Aricept Study Findings

The FDA approved ARICEPT based on evidence from four randomized trials with similar results. The longest of the trials included 473 people with mild-to-moderate Alzheimer’s Disease (average MMSE score was 19 out of 30) who were an average of 73 years old; about half were women. Researchers randomly assigned participants to take ARICEPT 5 mg, ARICEPT 10 mg, or a placebo (inactive sugar pill) for about **6 months**. Here’s what happened:

ARICEPT 5 mg **ARICEPT 10 mg** **Placebo**
(5 mg at bedtime) **(10 mg at bedtime)** **(No drug)** vs.

How did ARICEPT help?*

Doctor’s rating of change in dementia

Ratings were about the same for the 5-mg and 10-mg doses. For some people, **ARICEPT helped more than a placebo**, but the improvement was minimal. The biggest differences were in how many people were minimally improved, unchanged or worse.

Percent of people doctors rated as...

Markedly or moderately improved	5%	2%	vs.	4%
Minimally improved	21%	22%	vs.	6%
Unchanged	34%	45%	vs.	38%
Minimally worse	31%	25%	vs.	38%
Markedly or moderately worse	9%	6%	vs.	14%

Remember, learn and reason

The typical person taking ARICEPT scored slightly higher on a **71-point test** than those taking a placebo—**2.7 points higher for those taking 5 mg. and 3.2 points higher for those taking 10 mg ***

0.8 points 1.3 points vs. 1.9 points
better **better** **worse**

28 percent of those taking a placebo improved by the minimum noticeable amount (scores were better by 4 points or more). Compared to those taking a placebo, **12 percent more of those taking ARICEPT 5 mg. and 30 percent more of those taking ARICEPT 10 mg experienced this improvement.****

40% 58% vs. 28%

Quality of life

ARICEPT had no effect on quality of life in clinical trials.*

What were ARICEPT’s side effects?*

Side effects based on 1,025 people from the clinical trials.

Compared to those taking a PLACEBO:

1 percent more (5 mg dose) and 14 percent more (10 mg dose) had nausea	6%	19%	vs.	5%
3 percent more (5 mg dose) and 10 percent more (10 mg dose) had diarrhea	7%	14%	vs.	4%
5 percent more (10 mg dose) had vomiting	3%	8%	vs.	3%
2 percent more (5mg dose) and 5 percent more (10mg) has less appetite	3%	6%	vs.	1%
8 percent more (10 mg dose) had insomnia	5%	13%	vs.	5%
3 percent more (5 mg dose) and 6 percent more (10 mg dose) had muscle cramps	5%	8%	vs.	2%
1 percent more (5 mg dose) and 5 percent more (10 mg dose) had fatigue	4%	8%	vs.	3%

* Data from FDA Review Documents

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