

Clinical Advisory

Donepezil Gains Indication for Treatment of Severe Alzheimer's

First Product Approved for All Stages of Alzheimer's Disease

In October 2006, the FDA granted approval to donepezil hydrochloride (Aricept, Eisai Inc.) for the treatment of severe dementia in patients with Alzheimer's disease (AD). This important approval marked the first time that a product had been approved for all stages (mild, moderate, and severe) of this debilitating disease.¹ Donepezil, a cholinesterase inhibitor, was first approved in 1996 for the treatment of mild to moderate AD. While AD is a progressive and incurable disease, in the 10 years since its approval donepezil has been shown in numerous studies to benefit function and cognition in AD patients and slow the progression of symptoms.

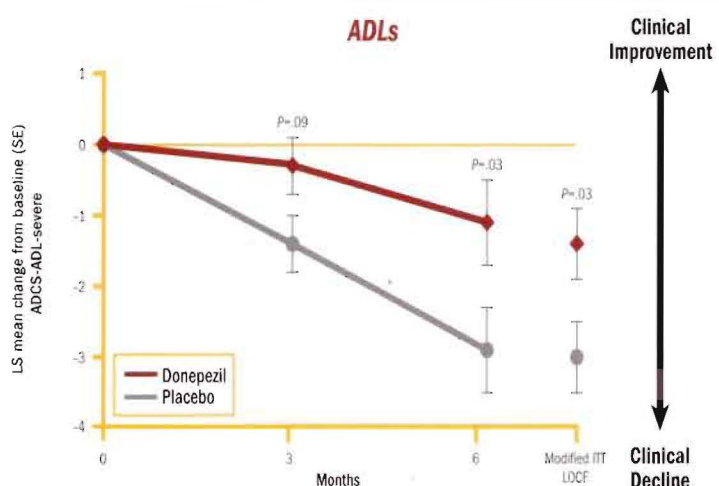
The indication for donepezil for severe AD was based primarily on the results of a 2006 study published in the journal *The Lancet*.²

The goal of the study was to examine the effectiveness of donepezil on cognition and activities of daily living (e.g., eating, walking, bathing, and more complex activities such as turning off lights and water, watching television, using a telephone) in patients with

severe AD. The 6-month, double-blind, parallel-group, placebo-controlled study enrolled 248 patients with severe AD who were living in nursing homes in Sweden. Patients were assigned to receive either donepezil 10 mg after 4 to 6 weeks of 5 mg therapy or placebo

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Donepezil in Patients With Severe Alzheimer's Disease: Double-Blind, Parallel-Group, Placebo-Controlled Study²



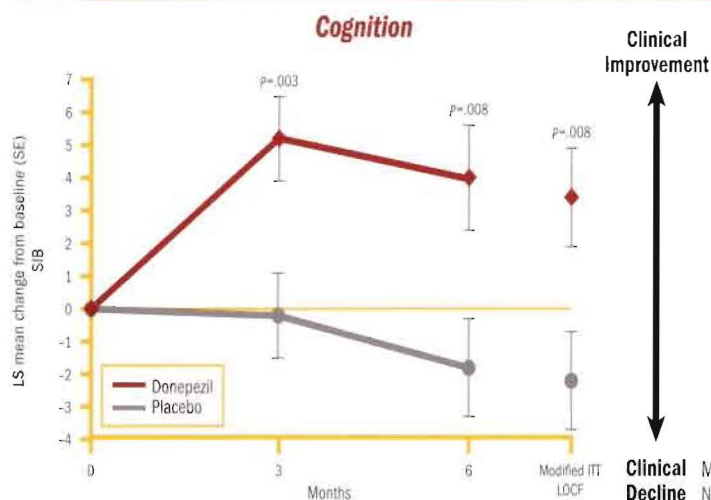
*ADLs = activities of daily living.

BASIC ADLs*

- bathing
- bowel/bladder function[†]
- eating
- getting dressed[†]
- grooming
- walking

INSTRUMENTAL ADLs

- alone away from home
- clearing dishes
- disposing of rubbish
- finding belongings
- getting around
- obtaining beverages
- running water
- turning off lights
- turning off water[†]
- turning on lights
- using the telephone
- watching television
- conversing [†]P<.05



Domains measured by the SIB

- attention
- construction
- language[†]
- memory
- orientation
- orientation to name
- praxis[†]
- social interaction
- visuospatial[†] [†]P<.05

Results from a 6-month, double-blind, randomized, placebo-controlled trial in patients with severe AD who were living in nursing homes. The primary outcome measures were the SIB and ADCS-ADL-severe. All patients were treated with donepezil 10 mg (following 4 weeks of treatment with the 5-mg dose) or placebo.

ARICEPT is indicated for the treatment of dementia of the Alzheimer's type. Efficacy has been demonstrated in patients with mild to moderate Alzheimer's disease, as well as in patients with severe Alzheimer's disease.

Please consult full prescribing information attached.

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Healthcare Information

