



Namzaric® (memantine/donepezil) – Expanded Indication

- On July 19, 2016, [Allergan and Adamas announced](#) the [FDA approval](#) of [Namzaric \(memantine/donepezil hydrochlorides\)](#) extended-release (ER) capsules, for the treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on 10 mg of donepezil hydrochloride once daily.
 - Previously, Namzaric was approved for the treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on memantine (5 mg to 10 mg twice daily or 14 mg to 28 mg ER once daily) and donepezil 10 mg.
 - With the expanded indication, Namzaric 7 mg/10 mg and 21 mg/10 mg ER capsules were also approved. Namzaric is currently available as 14 mg/10 mg and 28 mg/10 mg ER capsules.
- Namzaric is a combination of memantine hydrochloride, an N-methyl-D-aspartate (NMDA) receptor antagonist, and donepezil hydrochloride, an acetylcholinesterase inhibitor.
 - Memantine hydrochloride ER is the active ingredient in the currently marketed [Namenda XR®](#), which is indicated for the treatment of moderate to severe dementia of the Alzheimer's type.
 - Donepezil is the active ingredient in [Aricept®](#) and Aricept® ODT, which are indicated for the treatment of dementia of the Alzheimer's type. Donepezil is available generically.
- The effectiveness of Namzaric as a treatment for patients with moderate to severe Alzheimer's disease was established by demonstrating the bioequivalence of Namzaric with co-administered memantine hydrochloride ER and donepezil hydrochloride.
- The recommended maintenance dose of Namzaric is 28 mg/10 mg once daily.
 - For patients stabilized on donepezil and not currently on memantine, the recommended starting dose of Namzaric is 7 mg/10 mg, taken once a day in the evening. The dose should be increased in 7 mg increments of the memantine hydrochloride component to the recommended maintenance dose.
 - Patients stabilized on both donepezil (10 mg once daily) and memantine (10 mg twice daily or 28 mg ER once daily) can be switched to Namzaric 28 mg/10 mg, taken once a day in the evening.
- Allergan and Adamas plan to launch the two new strengths of Namzaric in September 2016.



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