

Adlarity® (donepezil) - New drug approval

- On March 14, 2022, <u>Corium announced</u> the FDA approval of <u>Adlarity (donepezil)</u>, for the treatment of mild, moderate, and severe dementia of the Alzheimer's type.
- Adlarity, an acetylcholinesterase inhibitor, is the first transdermal formulation of donepezil. It is
 also available generically as a <u>tablet</u> and as an <u>orally disintegrating tablet (ODT)</u>.
- The efficacy of Adlarity is based on a relative bioavailability study in healthy subjects comparing Adlarity transdermal system to Aricept tablets.
- Adlarity is contraindicated in patients with known hypersensitivity to donepezil or to piperidine
 derivatives and patients with a history of allergic contact dermatitis with use of Adlarity.
- Warnings and precautions for Adlarity include application site skin reactions; use during anesthesia; cardiovascular conditions; nausea and vomiting; peptic ulcer disease and gastrointestinal bleeding; genitourinary conditions; neurological conditions (seizures); and pulmonary conditions.
- The most common adverse reactions (> 5% with donepezil tablets and twice the placebo rate) were nausea, diarrhea, insomnia, vomiting, muscle cramps, fatigue, and anorexia.
- The recommended starting dosage of Adlarity is 5 mg/day. After 4 to 6 weeks, the dosage may be increased to the maximum recommended dosage of 10 mg/day. Adlarity should be administered as one transdermal system applied to the skin once weekly. Doses of the transdermal system higher than the 10 mg/day equivalent have not been evaluated.
 - Refer to the Adlarity drug label for instructions for switching to Adlarity from donepezil tablets or ODT.
- Corium plans to launch Adlarity in early Fall 2022. Adlarity will be available as a 5 mg/day and 10 mg/day transdermal system.



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