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Doxepin for insomnia: a systematic review of randomized placebo-controlled trials.

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Abstract

Doxepin, a sedating tricyclic drug, at 3 mg and 6 mg doses was recently approved by the U.S. food and drug administration (FDA) for the treatment of insomnia. The objective of this systematic review was to obtain a precise summary of the efficacy and safety of doxepin as a hypnotic. We searched key databases and trial registers up to March 2014 and contacted pharmaceutical companies and the FDA for unpublished data. A total of nine randomized placebo-controlled trials were analyzed. Six studies were on doxepin 1-6 mg/d, two on doxepin 25-300 mg/d, and one on ramelteon 8 mg and doxepin 3 mg combined. All low-dose studies were industry-sponsored. We found that low-dose doxepin had a small to medium effect size against placebo for sleep maintenance and sleep duration but not for sleep initiation at both immediate and short-term posttreatment. There was no significant next-day residual effect with low-dose doxepin. Headache and somnolence were the most common side effects. We concluded that low-dose doxepin for 1-2 nights appeared to be safe and effective in improving sleep. However, a clear conclusion on its short-term benefits and risks as well as withdrawal effects was not possible due to the small number of studies.

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