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Summary of Investigation Results

Memantine hydrochloride

June 16, 2020

Non-proprietary name

Memantine hydrochloride

Branded name (Marketing authorization holder)

Memary Tablets 5 mg, 10 mg, 20 mg, Memary OD Tablets 5 mg, 10 mg, 20 mg, Memary Dry Syrup 2% (Daiichi Sankyo Co., Ltd.), and the others

Indications

Control of the progression of moderate to severe dementia of the Alzheimer's type

Summary of revisions

"Bradyarrhythmia such as complete atrioventricular block and severe sinus bradycardia" should be added in the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of bradyarrhythmia have been reported in patients treated with memantine hydrochloride in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

Pharmaceuticals and Medical Devices Agency

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Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 4 cases involving bradyarrhythmia have been reported to date (including 2 cases for which a causal relationship between the drug and event was reasonably possible). No patient mortalities have been reported to date.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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