



Summary of investigation results

Memantine hydrochloride

August 6, 2015

Non-proprietary name

Memantine hydrochloride

Brand name (Marketing authorization holder)

Memary Tablets 5 mg, 10 mg, and 20 mg, and Memary OD Tablets 5 mg, 10 mg, and 20 mg
(Daiichi Sankyo Company, Limited)

Indications

Suppress progression of dementia symptoms in patients with moderate to severe Alzheimer's type dementia

Summary of revision

"Rhabdomyolysis" should be newly added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of rhabdomyolysis have been reported in patients treated with memantine hydrochloride in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 6 cases associated with rhabdomyolysis have been reported (including 5 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.