Summary of investigation results

Galantamine hydrobromide

October 20, 2015

Non-proprietary name

Galantamine hydrobromide

Brand name (Marketing authorization holder)

Reminyl Tablets 4 mg, 8 mg, and 12 mg, Reminyl OD Tablets 4 mg, 8 mg, and 12 mg, and Reminyl Oral Solution 4 mg/mL (Janssen Pharmaceutical K.K.)

Indications

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

Summary of revision

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

Background of the revision and investigation results

Cases of rhabdomyolysis have been reported in patients treated with galantamine hydrobromide 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 3 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp