This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of investigation results

galantamine hydrobromide

November 20, 2014

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

Suppression for progress of dementia symptoms in mild to moderate dementia of the Alzheimer's type

Summary of revision

'Acute generalised exanthematous pustulosis' should be added in Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of acute generalised exanthematous pustulosis have been reported in patients treated with galantamine hydrobromide in foreign countries, and the company core data sheet (CCDS)* has been updated. Following investigation results based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

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

No acute generalised exanthematous pustulosis-associated cases have been reported in Japan.

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*NOTE

CCDS is prepared by a marketing authorization holder and covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.

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