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.

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