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

Summary of investigation results

Memantine hydrochloride

February 17, 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
Prevent progression of dementia symptoms in patients with moderate to severe Alzheimer's type dementia

Summary of revision
'Hepatic function disorder and jaundice' should be added in the Clinically significant adverse reactions section.

Background of the revision and investigation results
Cases of hepatic function disorder and jaundice have been reported in patients treated with memantine in Japan. Following an investigation based on the opinions of expert advisors and 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 9 cases of adverse events suggestive of hepatic function disorder and jaundice have been reported (including 3 cases in which causality could not be ruled out). A total of 2 fatalities have been reported (including 1 case in which causality could not be ruled out).

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