

Translated by Pharmaceuticals and Medical Devices Agency



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.

Revision of Precautions Galantamine hydrobromide

October 20, 2015

Non-proprietary name

Galantamine hydrobromide

Safety measure

Precautions should be revised in the package insert.

In the Clinically significant adverse reaction subsection of the Adverse reaction section, the following text should be added (underlined parts are revised):

Rhabdomyolysis:

<u>Rhabdomyolysis may occur. Patients should be carefully monitored. If symptoms</u> <u>including myalgia, feelings of weakness, increased creatine kinase (creatine</u> <u>phosphokinase), or increased blood and urine myoglobin are observed, administration of</u> <u>this drug should be discontinued and appropriate measures should be adopted.</u>

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