Revision of Precautions
galantamine hydrobromide

November 20, 2014

Non-proprietary Name
galantamine hydrobromide

Safety measure
Precautions should be revised in the package insert.

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

Acute generalised exanthematous pustulosis:
Acute generalised exanthematous pustulosis may occur. Patients should be carefully monitored. If any abnormalities such as pyrexia, erythema, and many small pustules are observed, administration of this drug should be discontinued and appropriate measures should be taken.

NOTE
• This drug is designated to prepare a Drug Guide for Patients.