Revision of PRECAUTIONS
Paroxetine hydrochloride hydrate

July 8, 2014

Non-proprietary Name
Paroxetine hydrochloride hydrate

Safety measure
Precautions should be revised in the package inserts.

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

Anaphylaxis:
Anaphylaxis (rash, angioedema, dyspnoea, etc.) may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued, and appropriate measures should be taken.