



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**

# 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.