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*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

## Paliperidone palmitate

March 22, 2016

### **Non-proprietary name**

Paliperidone palmitate

### **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):

#### Anaphylaxis:

Anaphylaxis may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be adopted. Furthermore, cases of anaphylaxis have been reported in patients who have previously tolerated oral paliperidone or oral risperidone.