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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

### Duloxetine hydrochloride

April 23, 2015

#### **Non-proprietary name**

Duloxetine hydrochloride

#### **Safety measure**

Precautions should be revised in the package insert.

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

#### Neuroleptic malignant syndrome:

Neuroleptic malignant syndrome may occur. If any abnormalities such as fever, akinetic mutism, strong muscle rigidity, swallowing difficult, tachycardia, blood pressure fluctuation, diaphoresis, increased white blood cell count, increased serum creatine kinase (creatin phosphokinase), etc. are observed, administration of this drug should be discontinued. Then whole-body control such as body cooling and rehydration should be conducted, and appropriate measures should be taken. In addition, decreased kidney function with myoglobinuria may lead to acute kidney injury, and caution should therefore be exercised.