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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

## Mirabegron

March 22, 2016

### **Non-proprietary name**

Mirabegron

### **Safety measure**

Precautions should be revised in the package insert.

In the Important Precautions section, the following text should be added (underlined parts are revised):

This drug may increase blood pressure. Blood pressure should be measured periodically before and during treatment with this drug.

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

#### Hypertension:

Mirabegron may increase blood pressure. Cases of systolic blood pressure greater than or equal to 180 mmHg or diastolic blood pressure greater than or equal to 110 mmHg have been reported with this drug. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be adopted.