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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** Tramadol hydrochloride, Tramadol hydrochloride/acetaminophen

July 7, 2015

## Non-proprietary name

- a. Tramadol hydrochloride (OD tablets, Capsules, and Injection)
- b. Tramadol hydrochloride/acetaminophen

## Safety measure

Precautions should be revised in the package insert.

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

Respiratory depression:

Respiratory depression 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.

NOTE

Injection formula is designated to prepare a Drug Guide for Patients.

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