



*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 (oral dosage form)

July 4, 2017

## Non-proprietary name

Tramadol hydrochloride (oral dosage form)

## 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 should not be used in children younger than 12 years old because serious respiratory depression may occur (see Pediatric Use).

This drug should not be used in patients younger than 18 years old who are obese or have obstructive sleep apnoea syndrome or serious lung disease because the risk of serious respiratory depression may increase.

In the Pediatric Use section, the following text should be revised (underlined parts are revised):

The safety of this drug in children 12 years old and older has not been established (no clinical experience).

Then the following text should be added (underlined parts are revised):

This drug should not be used in children younger than 12 years old (Overseas there have been reports that the risk of serious respiratory depression, including death, is high in children younger than 12 years old).