

Published by
Ministry of Health, Labour and Welfare



Translated by
Pharmaceuticals and Medical Devices Agency



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)

Tramadol hydrochloride/acetaminophen

July 9, 2019

Therapeutic category

Antipyretics and analgesics, anti-inflammatory agents

Non-proprietary name

Tramadol hydrochloride (oral dosage form), tramadol hydrochloride/acetaminophen

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Contraindications (N/A)	Contraindications <u>Children younger than 12 years old</u>
Important Precautions <u>This drug should not be used in children younger than 12 years old because serious respiratory depression may occur.</u>	Important Precautions (deleted)

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) (N/A)	2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) <u>Children younger than 12 years old</u>

N/A: Not Applicable, because the section is not included in the current package insert.

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