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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 (injection)

July 9, 2019

### **Therapeutic category**

Antipyretics and analgesics, anti-inflammatory agents

### **Non-proprietary name**

Tramadol hydrochloride (injection)

### **Safety measure**

Precautions should be revised in the package insert.

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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
<p>Contraindications (N/A)</p> <p>Important Precautions <u>This drug should not be used in children younger than 12 years old because serious respiratory depression may occur.</u></p> <p><u>This drug should not be used in patients younger than 18 years old for pain relief after tonsillectomy or adenoidectomy because the risk of serious respiratory depression may increase.</u></p>	<p><u>Contraindications</u> <u>Children younger than 12 years old</u></p> <p><u>Use in patients younger than 18 years old for pain relief after tonsillectomy or adenoidectomy</u></p> <p>Important Precautions (deleted)</p>

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

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<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.1 Patients with Complication or History of Diseases, etc.  <u>Patients younger than 18 years old and after tonsillectomy or adenoidectomy</u>  <u>This drug should not be used for pain relief. The risk of serious respiratory depression may increase.</u></p> <p>9.7 Pediatric use  <u>Children after tonsillectomy or adenoidectomy</u>  <u>This drug should not be used for pain relief. The risk of serious respiratory depression may increase.</u></p>	<p><u>Use in patients younger than 18 years old for pain relief after tonsillectomy or adenoidectomy</u></p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.1 Patients with Complication or History of Diseases, etc.  (deleted)</p> <p>9.7 Pediatric use  (deleted)</p>
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N/A: Not Applicable, because the section is not included in the current package insert.

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