

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

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

Preparations containing ibuprofen (OTC drugs)

Preparations containing naproxen (guidance-mandatory drugs)

**Preparations containing loxoprofen sodium hydrate
(oral dosage form) (OTC drugs, guidance-mandatory drugs)**

October 8, 2024

Therapeutic category

Cold medicines

Antipyretics and analgesics

Non-proprietary name

Preparations containing ibuprofen (OTC drugs)

Preparations containing naproxen (guidance-mandatory drugs)

Preparations containing loxoprofen sodium hydrate (oral dosage form) (OTC drugs, guidance-mandatory drugs)

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision						
<p>Consultation</p> <p>If the following symptoms are observed after taking this drug, these may be adverse reactions. In such cases, the use of this drug should be immediately discontinued, and a physician, dentist¹⁾, pharmacist or registered salesclerk²⁾ should be consulted, presenting them with this document.</p> <p>The following serious symptoms may occur rarely. In such cases, medical attention should be sought immediately.</p> <p>(N/A)</p>	<p>Consultation</p> <p>If the following symptoms are observed after taking this drug, these may be adverse reactions. In such cases, the use of this drug should be immediately discontinued, and a physician, dentist¹⁾, pharmacist or registered salesclerk²⁾ should be consulted, presenting them with this document.</p> <p>The following serious symptoms may occur rarely. In such cases, medical attention should be sought immediately.</p> <table border="1"> <tr> <th>Name of symptoms</th><th>Symptoms</th></tr> <tr> <td><u>Myocardial infarction</u></td><td><u>Tight chest pain, difficulty breathing, and cold sweat may occur.</u></td></tr> <tr> <td><u>Cerebrovascular disorder</u></td><td><u>Some symptoms such as decrease in consciousness/loss of consciousness, difficulty in moving unilateral extremities, headache, vomiting, dizziness, difficulty speaking, and speech apraxia may occur suddenly.</u></td></tr> </table>	Name of symptoms	Symptoms	<u>Myocardial infarction</u>	<u>Tight chest pain, difficulty breathing, and cold sweat may occur.</u>	<u>Cerebrovascular disorder</u>	<u>Some symptoms such as decrease in consciousness/loss of consciousness, difficulty in moving unilateral extremities, headache, vomiting, dizziness, difficulty speaking, and speech apraxia may occur suddenly.</u>
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<u>Cerebrovascular disorder</u>	<u>Some symptoms such as decrease in consciousness/loss of consciousness, difficulty in moving unilateral extremities, headache, vomiting, dizziness, difficulty speaking, and speech apraxia may occur suddenly.</u>						
<p>1) "Dentist" should be listed only for antipyretics and analgesics.</p> <p>2) "Registered salesclerk" should be listed only for preparations containing ibuprofen.</p>	<p>1) "Dentist" should be listed only for antipyretics and analgesics.</p> <p>2) "Registered salesclerk" should be listed only for preparations containing ibuprofen.</p>						

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.