

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

Acemetacin, Indometacin (suppositories), Indometacin farnesil, Oxaprozin, Tiaramide hydrochloride, Proglumetacin maleate, Meloxicam

October 8, 2024

Therapeutic category

Antipyretics, analgesics and anti-inflammatory agents

Non-proprietary name

Acemetacin

Indometacin (suppositories)

Indometacin farnesil

Oxaprozin

Tiaramide hydrochloride

Proglumetacin maleate

Meloxicam

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revised
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Myocardial infarction, cerebrovascular disorder</u> <u>Cardiovascular thromboembolic events including myocardial</u> <u>infarction and cerebrovascular disorder may occur.</u>

(Reference) Summary of Study Results Using National Database of Health Insurance Claims and Specific Health Checkup of Japan (NDB)

(Evaluation of the risk of cardiovascular events due to non-steroidal anti-inflammatory drugs using NDB)

[https:// www.pmda.go.jp/files/000270715.pdf](https://www.pmda.go.jp/files/000270715.pdf)

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