

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

Ketoprofen (injections, suppositories)

October 8, 2024

Therapeutic category

Antipyretics, analgesics and anti-inflammatory agents

Non-proprietary name

Ketoprofen (injections, suppositories)

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revised
<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p>Pregnant women (excluding the third trimester) or women who may be pregnant</p> <p>This drug should be administered only when the therapeutic benefits are considered to outweigh the risks. If administration is deemed necessary, caution should be exercised such as limiting the drug to the minimum effective use and checking amniotic fluid volume as necessary. It has been reported that oligohydramnios occurred in pregnant women who had been administered a dermatologic preparation of ketoprofen in their second trimester of pregnancy. In addition, renal impairment and decreased urine output in fetuses as well as accompanying oligohydramnios have been reported following use of cyclooxygenase inhibitors (oral dosage form or suppository) in pregnant women.</p> <p>11. ADVERSE REACTIONS</p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p>Pregnant women (excluding the third trimester) or women who may be pregnant</p> <p>This drug should be administered only when the therapeutic benefits are considered to outweigh the risks. If administration is deemed necessary, caution should be exercised such as limiting the drug to the minimum effective use and checking amniotic fluid volume <u>and findings suggestive of constriction of the foetal ductus arteriosus with consideration given to the gestational age and duration of administration</u> as necessary. It has been reported that oligohydramnios occurred in pregnant women who had been administered a dermatologic preparation of ketoprofen in their second trimester of pregnancy. In addition, renal impairment and decreased urine output in fetuses as well as accompanying oligohydramnios have been reported following use of cyclooxygenase inhibitors (oral dosage form or suppository) in pregnant women. <u>It has been reported that constriction of the foetal ductus arteriosus occurred in pregnant women who had been administered cyclooxygenase inhibitors (preparations with expected systemic effects) in their second trimester of pregnancy.</u></p> <p>11. ADVERSE REACTIONS</p>

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