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

Zaltoprofen

October 8, 2024

Therapeutic category

Antipyretics, analgesics and anti-inflammatory agents

Non-proprietary name

Zaltoprofen

Safety measure PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revised
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC
BACKGROUNDS	BACKGROUNDS
9.5 Pregnant Women	9.5 Pregnant Women
Pregnant women or women who may be pregnant	Pregnant women or women who may be pregnant
This drug should be administered only if the potential therapeutic	This drug should be administered only if the potential therapeutic
benefits are considered to outweigh the potential risks. If	benefits are considered to outweigh the potential risks. If
administration is deemed necessary, caution should be exercised	administration is deemed necessary, caution should be exercised
such as limiting the drug to the minimum effective use and checking	such as limiting the drug to the minimum effective use and checking
amniotic fluid volume as necessary. Renal impairment and	amniotic fluid volume and findings suggestive of constriction of the
decreased urine output in foetuses as well as accompanying	foetal ductus arteriosus with consideration given to the gestational
oligohydramnios have been reported following use of	age and duration of administration as necessaryRenal impairment
cyclooxygenase inhibitors (oral dosage form or suppository) in	and decreased urine output in foetuses as well as accompanying
pregnant women.	oligohydramnios have been reported following use of
	cyclooxygenase inhibitors (oral dosage form or suppository) in
	pregnant women. It has been reported that constriction of the foetal
	ductus arteriosus occurred in pregnant women who had been
	administered cyclooxygenase inhibitors in their second and/or third
	trimester of pregnancy with a higher risk known in women exposed
	to the drug in their third trimester.
	11. ADVERSE REACTIONS
11. ADVERSE REACTIONS	11.1 Clinically Significant Adverse Reactions
11.1 Clinically Significant Adverse Reactions	Myocardial infarction, cerebrovascular disorder
(N/A)	Cardiovascular thromboembolic events including myocardial

infarction and cerebrovascular disorder may occur.

(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

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