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

Flufenamate aluminum

October 8, 2024

Therapeutic category Antipyretics, analgesics and anti-inflammatory agents

Non-proprietary name

Flufenamate aluminum

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 should be	Pregnant women or women who may be pregnant should be
administered this drug only if the potential therapeutic benefits are	administered this drug only if the potential therapeutic benefits are
considered to outweigh the potential risks. If administration is	considered to outweigh the potential risks. If administration is
deemed necessary, caution should be exercised such as limiting the	deemed necessary, caution should be exercised such as limiting the
drug to the minimum effective use and checking amniotic fluid	drug to the minimum effective use and checking amniotic fluid
volume as necessary. Renal impairment and decreased urine output	volume and findings suggestive of constriction of the foetal ductus
in foetuses as well as accompanying oligohydramnios have been	arteriosus with consideration given to the gestational age and
reported following use of cyclooxygenase inhibitors (oral dosage	duration of administration as necessary. Renal impairment and
form or suppository) in pregnant women.	decreased urine output in foetuses 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</u>
	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
(N/A)	Myocardial infarction, cerebrovascular disorder
	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.