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 BACKGROUNDS 9.5 Pregnant Women Pregnant women or women who may be pregnant should be administered this drug only if the potential therapeutic benefits are considered to outweigh the potential 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. Renal impairment and 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.	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.5 Pregnant Women Pregnant women or women who may be pregnant should be administered this drug only if the potential therapeutic benefits are considered to outweigh the potential 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. Renal impairment and 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 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.</u>
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>

	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.