Revision of PRECAUTIONS

Esflurbiprofen/mentha oil

October 8, 2024

Therapeutic category

Analgesics, anti-itchings, astrigents and anti-inflammatory agents

Non-proprietary name

Esflurbiprofen/mentha oil

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 (excluding the third trimester) or women who may be pregnant 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. The safety of this drug administered during pregnancy has not been established. 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 (excluding the third trimester) or women who may be pregnant 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. The safety of this drug administered during pregnancy has not been established. 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 women who had been administered cyclooxygenase inhibitors (preparations with expected systemic effects) in their second trimester of pregnancy.</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>

	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.