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

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	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC
BACKGROUNDS	BACKGROUNDS
9.5 Pregnant Women	9.5 Pregnant Women
Pregnant women (excluding the third trimester) or women who may	Pregnant women (excluding the third trimester) or women who may
be pregnant	be pregnant
This drug should be administered only when the therapeutic benefits	This drug should be administered only when the therapeutic benefits
are considered to outweigh the risks. If administration is deemed	are considered to outweigh the risks. If administration is deemed
necessary, caution should be exercised such as limiting the drug to	necessary, caution should be exercised such as limiting the drug to
the minimum effective use and checking amniotic fluid volume as	the minimum effective use and checking amniotic fluid volume <u>and</u>
necessary. The safety of this drug administered during pregnancy	findings suggestive of constriction of the foetal ductus arteriosus with
has not been established. Renal impairment and decreased urine	consideration given to the gestational age and duration of
output in foetuses as well as accompanying oligohydramnios have	administration as necessary. The safety of this drug administered
been reported following use of cyclooxygenase inhibitors (oral	during pregnancy has not been established. Renal impairment and
dosage 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 women who had been administered
	cyclooxygenase inhibitors (preparations with expected systemic
	effects) in their second trimester of pregnancy.
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 myocarc	lial
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.