

*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

## Indometacin (topical preparations excluding patches)

October 8, 2024

### **Therapeutic category**

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

### **Non-proprietary name**

Indometacin (topical preparations excluding patches)

### **Safety measure**

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revised
<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p>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. Long-term treatment at a high dose or with extensive administration should be avoided. It has been reported that constriction of the foetal ductus arteriosus occurred in pregnant women who had used <u>other dermatologic preparations of NSAIDs</u> in their third trimester of pregnancy. In addition, renal impairment and decreased urine output in fetuses as well as accompanying oligohydramnios have been reported following use of cyclooxygenase inhibitors (oral dosage form or suppository) in pregnant women.</p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p>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. Long-term treatment at a high dose or with extensive administration should be avoided. It has been reported that constriction of the foetal ductus arteriosus occurred in pregnant women who had used <u>cyclooxygenase inhibitors</u> in their <u>second and/or</u> third trimester of pregnancy. In addition, renal impairment and decreased urine output in fetuses as well as accompanying oligohydramnios have been reported following use of cyclooxygenase inhibitors (oral dosage form or suppository) in pregnant women.</p>