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Translated by
Pharmaceuticals and Medical Devices Agency



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 (agents for epidermis), ketoprofen (agents for epidermis), diclofenac sodium (agents for epidermis), piroxicam (agents for epidermis), felbinac, flurbiprofen (agents for epidermis), loxoprofen sodium hydrate (agents for epidermis), salicylic acid (dry powder, ointment, patches)

February 25, 2021

Therapeutic category

Analgesics, anti-itchings, astringents and anti-inflammatory agents, anti-dermoinfectives, emollients

Non-proprietary name

Indometacin, ketoprofen, diclofenac sodium, piroxicam, felbinac, flurbiprofen, loxoprofen sodium hydrate, salicylic acid

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Safety measure

Precautions should be revised in the package insert.

Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Use during Pregnancy, Delivery or Lactation (N/A)	Use during Pregnancy, Delivery or Lactation <u>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.</u>

N/A: Not Applicable, because the section is not included in the current package insert.

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