Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Ketoprofen (suppository)

February 25, 2021

Therapeutic category

Antipyretics, analgesics and anti-inflammatory agents

Non-proprietary name

Ketoprofen

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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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 This drug should be administered to pregnant women (excluding those in their third trimester) or women who may be pregnant only when the therapeutic benefits are considered to outweigh the risks. The safety of this drug administered during pregnancy has not been established. Onset of oligohydramnios following administration of a ketoprofen agent(s) for epidermis in women in their second trimester of pregnancy has been reported. Caution should be exercised such as limiting the drug to the minimum effective use.	Use during Pregnancy, Delivery or Lactation This drug should be administered to pregnant women (excluding those in their third trimester) or women who may be pregnant only when the therapeutic benefits are considered to outweigh the risks. If such administration is deemed necessary, caution should be exercised such as limiting to the minimum effective use and monitoring amniotic fluid as necessary. The safety of this drug administered during pregnancy has not been established. Onset of oligohydramnios following administration of a ketoprofen agent(s) for epidermis in women in their second trimester of pregnancy has been reported. Renal impairment and decreased urine output in foetuses as well as accompanying oligohydramnios have also been reported following use of cyclooxygenase inhibitors (oral dosage form or suppository) in pregnant women.

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

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9.5 Pregnant Women Pregnant women (excluding those in their second or third trimester) or women who may be pregnant This drug should be administered only when the therapeutic benefits are considered to outweigh the risks.	9.5 Pregnant Women Pregnant women (excluding those in their 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 such administration is deemed necessary, caution should be exercised such as limiting to the minimum effective use and monitoring amniotic fluid as necessary. Onset of oligohydramnios following use of a ketoprofen agent(s) for epidermis in women in the second trimester of pregnancy has been reported. Renal impairment and decreased urine output in foetuses as well as accompanying oligohydramnios have also been reported following use of cyclooxygenase inhibitors (oral dosage form or suppository) in pregnant women.
Second trimester of pregnancy This drug should be administered only when the therapeutic benefits are considered to outweigh the risks. Caution should be exercised such as limiting to the minimum effective use. Onset of oligohydramnios following use of a ketoprofen agent(s) for epidermis in women in the second trimester of pregnancy has been reported.	(deleted)

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