Published by Ministry of Health, Labour and Welfare 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 Ketoprofen (injections)

February 25, 2021

Therapeutic category

Antipyretics, analgesics and anti-inflammatory agents

62

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

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3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan E-mail: <u>safety.info@pmda.go.jp</u> 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	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC
BACKGROUNDS	BACKGROUNDS
9.5 Pregnant Women	9.5 Pregnant Women
Women in the second trimester of pregnancy	Pregnant women (excluding those in their third trimester) or women
This drug should be administered only when the therapeutic	who may be pregnant
benefits are considered to outweigh the risks. Caution should be	This drug should be administered only when the therapeutic
exercised such as limiting to the minimum effective use. Onset of	benefits are considered to outweigh the risks. If such administration
oligohydramnios following use of a ketoprofen agent(s) for	is deemed necessary, caution should be exercised such as limiting
epidermis in women in the second trimester of pregnancy has been	to the minimum effective use and monitoring amniotic fluid as
reported.	necessary. Onset of oligohydramnios following use of a ketoprofen
	agent(s) for epidermis in women in the second trimester of
	pregnancy has been reported. <u>Renal impairment and decreased</u>
	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.
Women who are pregnant (excluding those in their second or third	(deleted)
trimester) or women who may be pregnant	
This drug should be administered only when the therapeutic	
benefits are considered to outweigh the risks.	

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