

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

Ketoprofen (dermatologic preparation)

October 8, 2024

Therapeutic category

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

Non-proprietary name

Ketoprofen (dermatologic preparation)

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revised
<p data-bbox="226 256 1111 336">9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p data-bbox="226 352 506 384">9.5 Pregnant Women</p> <p data-bbox="226 400 1111 480">Pregnant women (excluding the third trimester) or women who may be pregnant</p> <p data-bbox="226 496 1111 919">This drug should be administered only when the therapeutic benefits are considered to outweigh the risks. Caution should be exercised such as limiting the drug to the minimum effective use. It has been reported that oligohydramnios occurred in pregnant women who had used a dermatologic preparation of ketoprofen in their second trimester of pregnancy. In addition, renal impairment and 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.</p>	<p data-bbox="1111 256 1995 336">9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p data-bbox="1111 352 1391 384">9.5 Pregnant Women</p> <p data-bbox="1111 400 1995 480">Pregnant women (excluding the third trimester) or women who may be pregnant</p> <p data-bbox="1111 496 1995 1114">This drug should be administered only when the therapeutic benefits are considered to outweigh the risks. Caution should be exercised such as limiting the drug to the minimum effective use. It has been reported that oligohydramnios occurred in pregnant women who had used a dermatologic preparation of ketoprofen in their second trimester of pregnancy. In addition, renal impairment and 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 ductus arteriosus occurred in pregnant women who had used cyclooxygenase inhibitors (preparations with expected systemic effects) in their second trimester of pregnancy.</u></p>