

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

Glycol salicylate/l-menthol, Methyl salicylate

Methyl salicylate/dl-camphor/capsicum extract

Methyl salicylate/dl-camphor/l-menthol

Methyl salicylate/l-menthol/dl-camphor/glycyrrhetinic acid

Felbinac, Heparinoid/adrenal extract/salicylic acid, Salicylic acid

October 8, 2024

Therapeutic category

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

Anti-dermoinfectives

Emollients (including caustics)

Non-proprietary name

Glycol salicylate/l-menthol

Methyl salicylate

Methyl salicylate/dl-camphor/capsicum extract

Methyl salicylate/dl-camphor/l-menthol

Methyl salicylate/l-menthol/dl-camphor/glycyrrhetinic acid

Felbinac

Heparinoid/adrenal extract/salicylic acid

Salicylic acid

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revised
<p data-bbox="226 255 1108 335">9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p data-bbox="226 351 504 383">9.5 Pregnant Women</p> <p data-bbox="226 399 1108 726">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. 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="1120 255 2004 335">9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p data-bbox="1120 351 1400 383">9.5 Pregnant Women</p> <p data-bbox="1120 399 2004 869">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. 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 been administered cyclooxygenase inhibitors in their second and/or third trimester of pregnancy.</u></p>