

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

Ibuprofen piconol, glycol salicylate/l-menthol, methyl salicylate/dl-camphor/capsicum extract, methyl salicylate/dl-camphor/l-menthol, methyl salicylate/glycol salicylate/l-menthol/d-camphor/diphenhydramine/benzyl nicotinate, methyl salicylate/l-menthol/dl-camphor/glycyrrhetic acid, suprofen

February 25, 2021

Therapeutic category

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

Non-proprietary name

Ibuprofen piconol, glycol salicylate/l-menthol, methyl salicylate/dl-camphor/capsicum extract, methyl salicylate/dl-camphor/l-menthol, methyl

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

salicylate/glycol salicylate/l-menthol/d-camphor/diphenhydramine/benzyl nicotinate, methyl salicylate/l-menthol/dl-camphor/glycyrrhetic acid, suprofen

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>This drug should be administered to pregnant women or women who may be pregnant only when the therapeutic benefits are considered to outweigh the risks. The safety of this drug in pregnant women has not been established.</u> <u>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>

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

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp