

Published by  
Ministry of Health, Labour and Welfare



Translated by  
Pharmaceuticals and Medical Devices Agency



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*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

## Methyl salicylate

February 25, 2021

### **Therapeutic category**

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

### **Non-proprietary name**

Methyl salicylate

### **Safety measure**

Precautions should be revised in the package insert.

**Pharmaceuticals and Medical Devices Agency**

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

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
(N/A)	<p><u>Use during Pregnancy, Delivery or Lactation</u></p> <p><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></p> <p><u>Renal impairment and decreased urine output in fetuses as well as accompanying oligohydramnios have been reported following use of cyclooxygenase inhibitors (oral dosage form or suppository) in pregnant women.</u></p>

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

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