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 Heparinoid/adrenal extract/salicylic acid

February 25, 2021

## Therapeutic category

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

## Non-proprietary name

Heparinoid/adrenal extract/salicylic acid

## Safety measure

Precautions should be revised in the package insert.

**Pharmaceuticals and Medical Devices Agency** 

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                        |
| The safety of this drug <u>used during pregnancy</u> has not been | This drug should be administered to pregnant women or women        |
| established.  | 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.                           |
|   |  |
| (N/A)   | 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.   |

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