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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

Aspirin (preparations indicated for antipyresis, analgesia, anti-inflammation, prevention of thrombus/embolus formation, Kawasaki disease)

February 25, 2021

Therapeutic category

Antipyretics, analgesics and anti-inflammatory agents

Other agents relating to blood and body fluids

Non-proprietary name

Aspirin

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
<p>Use during Pregnancy, Delivery or Lactation (N/A)</p>	<p>Use during Pregnancy, Delivery or Lactation <u>When this drug is administered to pregnant women (excluding those within 12 weeks before due date) or women who may be pregnant, caution should be exercised such as limiting to the minimum effective use and monitoring amniotic fluid as necessary for indications other than Kawasaki disease. 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></p>

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.5 Pregnant Women Pregnant women (excluding those within 12 weeks before due date) or women who may be pregnant This drug should be administered only when the therapeutic</p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.5 Pregnant Women Pregnant women (excluding those within 12 weeks before due date) or women who may be pregnant <u><common to all indications></u></p>

benefits are considered to outweigh the risks.

(1) This drug should be administered only when the therapeutic benefits are considered to outweigh the risks. 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.

<Indications other than Kawasaki disease>

(2) If administration is deemed necessary, caution should be exercised such as limiting to the minimum effective use and monitoring amniotic fluid as necessary.