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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

Isopropylantipyrine

February 25, 2021

Therapeutic category

Antipyretics, analgesics and anti-inflammatory agents

Non-proprietary name

Isopropylantipyrine

Safety measure

Precautions should be revised in the package insert.

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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</p> <p>Teratogenic effects have been reported in animal studies.</p> <p>Administration of this drug is not recommended in pregnant women or women who may be pregnant.</p>	<p>Use during Pregnancy, Delivery or Lactation</p> <p>Teratogenic effects have been reported in animal studies.</p> <p>Administration of this drug is not recommended in pregnant women or women who may be pregnant. <u>If such administration is deemed necessary, caution should be exercised such as limiting to the minimum effective use and monitoring amniotic fluid as necessary.</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>

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