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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

Dibucaine hydrochloride/sodium salicylate/calcium bromide, bucolome, flufenamate aluminum, mofezolac

February 25, 2021

Therapeutic category

Antipyretics, analgesics and anti-inflammatory agents

Non-proprietary name

Dibucaine hydrochloride/sodium salicylate/calcium bromide, bucolome, flufenamate aluminum, mofezolac

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>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 administered during pregnancy has not been established.</p>	<p>Use during Pregnancy, Delivery or Lactation</p> <p>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. <u>If administration of this drug is deemed necessary, caution should be exercised such as limiting to the minimum effective use and monitoring amniotic fluid as necessary.</u> The safety of this drug administered during pregnancy has not been established. <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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