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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Zaltoprofen

February 25, 2021

Therapeutic category

Antipyretics, analgesics and anti-inflammatory agents

Non-proprietary name

Zaltoprofen

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

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
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.5 Pregnant Women 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. Foetal ductus arteriosus systole	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.5 Pregnant Women Pregnant women or women who may be pregnant This drug should be administered only when the therapeutic benefits are considered to outweigh the risks. If such administration

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following administration of this drug in late pregnancy has been reported in animal studies with rats.	is deemed necessary, caution should be exercised such as limiting to the minimum effective use and monitoring amniotic fluid as necessary. 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. Foetal ductus arteriosus systole following administration of this drug in late pregnancy has been reported in animal studies with rats.