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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Aspirin (preparations indicated for prevention of thrombus/embolus formation, Kawasaki disease), aspirin/dialuminate (81 mg), aspirin/lansoprazole, clopidogrel sulfate/aspirin

February 25, 2021

Therapeutic category

Other agents relating to blood and body fluids

Non-proprietary name

Aspirin, aspirin/dialuminate, aspirin/lansoprazole, clopidogrel sulfate/aspirin

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 (excluding those within 12 weeks before due date) or women who may be pregnant only when the therapeutic benefits are considered to outweigh the risks.	Use during Pregnancy, Delivery or Lactation This drug should be administered to pregnant women (excluding those within 12 weeks before due date) or women who may be pregnant only when the therapeutic benefits are considered to outweigh the risks. <u>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>

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 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 benefits are considered to outweigh the risks.	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 benefits are considered to outweigh the risks. <u>Renal impairment and decreased urine output in foetuses as well as accompanying oligohydramnios have been reported following use of</u>

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