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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

Aspirin/vonoprazan fumarate

February 25, 2021

Therapeutic category

Other agents relating to blood and body fluids

Non-proprietary name

Aspirin/vonoprazan fumarate

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, 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</p> <p>9.5 Pregnant Women</p> <p>Pregnant women (excluding those within 12 weeks before due date) or women who may be pregnant</p> <p>This drug should be administered only when the therapeutic benefits are considered to outweigh the risks.</p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p>Pregnant women (<u>with</u> those within 12 weeks before due date <u>excluded</u>) or women who may be pregnant</p> <p>This drug should be administered only when the therapeutic benefits are considered to outweigh the risks. <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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