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Revision of Precautions

Vonoprazan fumarate

October 29, 2019

Therapeutic category

Peptic ulcer agents

Non-proprietary name

Vonoprazan fumarate

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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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
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Pancytopenia, agranulocytosis, leukopenia, or thrombocytopenia may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.</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
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (common to all indications) (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (common to all indications) <u>Pancytopenia, agranulocytosis, leukopenia, and thrombocytopenia</u>

N/A: Not Applicable, because the section is not included in the current package insert.

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