Published by
Ministry of Health, Labour and Welfare

Translated by
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

Vonoprazan fumarate/amoxicillin hydrate/clarithromycin

Vonoprazan fumarate/amoxicillin hydrate/metronidazole

October 29, 2019

Therapeutic category

Antibiotics-miscellaneous

Non-proprietary name

Vonoprazan fumarate/amoxicillin hydrate/clarithromycin, vonoprazan fumarate/amoxicillin hydrate/metronidazole

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
(vonoprazan fumarate) Adverse Reactions Clinically Significant Adverse Reactions (N/A)	(vonoprazan fumarate) 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>

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

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