Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Vonoprazan fumarate/amoxicillin hydrate/clarithromycin

Vonoprazan fumarate/amoxicillin hydrate/metronidazole

October 6, 2020

Therapeutic category

Other antibiotic preparations

Non-proprietary name

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

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 (Vonoprazan fumarate) Clinically Significant Adverse Reactions (N/A)	Adverse Reactions (Vonoprazan fumarate) Clinically Significant Adverse Reactions <u>Shock or anaphylaxis 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> <u>Hepatic impairment 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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