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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

Vonoprazan fumarate/amoxicillin hydrate/clarithromycin

Vonoprazan fumarate/amoxicillin hydrate/metronidazole

November 16, 2022

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
<p>Important Precautions (Amoxicillin hydrate)</p> <p>Shock <u>may occur</u>. A thorough medical interview should be conducted.</p>	<p>Important Precautions (Amoxicillin hydrate)</p> <p><u>No methods are currently available for predicting onset of shock, anaphylaxis, or acute coronary syndrome accompanying allergic reaction with reasonable certainty.</u> A thorough medical interview should be conducted <u>regarding patient's medical history of these events, etc. in advance.</u> In addition, it should be ensured that a <u>history of allergy to antibiotics was checked.</u></p>
<p>Adverse Reactions (Amoxicillin hydrate)</p> <p>Clinically Significant Adverse Reactions (N/A)</p>	<p>Adverse Reactions (Amoxicillin hydrate)</p> <p>Clinically Significant Adverse Reactions</p> <p><u>Acute coronary syndrome accompanying allergic reaction:</u> <u>Acute coronary syndrome accompanying allergic reaction 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></p>

(N/A): Not Applicable. No corresponding language is included in the current Precautions.

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p><Amoxicillin hydrate></p> <p>Shock <u>may occur</u>. A thorough medical interview should be conducted.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><Amoxicillin hydrate></p> <p>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><Amoxicillin hydrate></p> <p><u>No methods are currently available for predicting onset of shock, anaphylaxis, or acute coronary syndrome accompanying allergic reaction with reasonable certainty.</u> A thorough medical interview should be conducted <u>regarding patient's medical history of these events, etc. in advance.</u> In addition, it should be ensured that a <u>history of allergy to antibiotics was checked.</u></p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><Amoxicillin hydrate></p> <p><u>Acute coronary syndrome accompanying allergic reaction</u></p>

(N/A): Not Applicable. No corresponding language is included in the current Precautions.

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