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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Amoxicillin hydrate

November 16, 2022

Therapeutic category

Antibiotic preparations acting mainly on gram-positive and gram-negative bacteria

Non-proprietary name

Amoxicillin hydrate

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

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

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

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