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*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. The PMDA shall not be responsible for any consequences resulting from the use of this English version.*

# Revision of PRECAUTIONS

## Amoxicillin hydrate

## Potassium clavulanate/amoxicillin hydrate

May 8, 2024

### **Therapeutic category**

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

### **Non-proprietary name**

Amoxicillin hydrate

Potassium clavulanate/amoxicillin hydrate

### **Safety measure**

PRECAUTIONS should be revised.

**Pharmaceuticals and Medical Devices Agency**

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan  
E-mail: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)

Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p>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 on information including the patient's medical history of these events, etc. should be conducted in advance. In addition, it should be ensured that a history of allergy to antibiotics was checked.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p>No methods are currently available for predicting onset of shock, anaphylaxis, acute coronary syndrome accompanying allergic reaction, <u>or drug-induced enterocolitis syndrome</u> with reasonable certainty. A thorough medical interview on information including the patient's medical history of these events, etc. should be conducted in advance. In addition, it should be ensured that a history of allergy to antibiotics was checked.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><u>Drug-induced enterocolitis syndrome</u></p> <p><u>Allergic gastroenteritis (drug-induced enterocolitis syndrome) similar to food protein-induced enterocolitis accompanied by diarrhoea, lethargy, facial pallor, hypotension, abdominal pain, increased neutrophils, etc., with recurrent vomiting within several hours after administration as a main symptom, may occur. Cases have been reported mainly in children.</u></p>

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

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