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.
### 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 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.

### 11. ADVERSE REACTIONS

11.1 Clinically Significant Adverse Reactions

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<th>Current</th>
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| (N/A)   | Drug-induced enterocolitis syndrome  
Allergic gastroenteritis (drug-induced enterocolitis syndrome) similar to food protein-induced enterocolitis accompanied by diarrhea, 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. |

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