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Translated by
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

Ampicillin hydrate

Ampicillin sodium

May 9, 2023

Therapeutic category

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

Non-proprietary name

Ampicillin hydrate

Ampicillin sodium

Safety measure

Precautions should be revised.

Pharmaceuticals and Medical Devices Agency

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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-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS (N/A)</p> <p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)</p>	<p>8. IMPORTANT PRECAUTIONS <u>Hepatic impairment may occur. Periodic tests should be performed.</u></p> <p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Hepatic impairment</u> <u>Hepatic impairment accompanied by increased levels of AST and ALT, etc. may occur.</u></p>

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

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