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Translated by  
Pharmaceuticals and Medical Devices Agency



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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.*

# Revision of Precautions

## Ampicillin hydrate/cloxacillin sodium hydrate

## Ampicillin sodium/cloxacillin sodium hydrate

May 9, 2023

### **Therapeutic category**

Other antibiotic preparations

### **Non-proprietary name**

Ampicillin hydrate/cloxacillin sodium hydrate

Ampicillin sodium/cloxacillin sodium 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)

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
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Hepatic impairment accompanied by increased levels of AST and ALT, etc. may occur. Patients should be carefully monitored through methods such as periodic tests. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.</u>

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

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
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS <u>Hepatic impairment may occur. Periodic tests should be performed.</u>
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	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>

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

**Pharmaceuticals and Medical Devices Agency**