

Published by
Ministry of Health, Labour and Welfare



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

Cefazolin sodium Cefazolin sodium hydrate

August 29, 2023

Therapeutic category

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

Non-proprietary name

Cefazolin sodium

Cefazolin 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

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
<p>Important Precautions</p> <p>Since no methods are currently available for predicting onset of shock or anaphylaxis associated with this drug with reasonable certainty, the following measures should be taken.</p> <p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>(N/A)</p>	<p>Important Precautions</p> <p>Since no methods are currently available for predicting onset of shock, anaphylaxis, or <u>acute coronary syndrome accompanying allergic reaction</u> associated with this drug with reasonable certainty, the following measures should be taken.</p> <p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p><u>Acute coronary syndrome accompanying allergic reaction:</u> <u>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.</u></p>

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, 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</p> <p>Since no methods are currently available for predicting onset of</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p>Since no methods are currently available for predicting onset of</p>

Pharmaceuticals and Medical Devices Agency

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

<p>shock or anaphylaxis associated with this drug with reasonable certainty, the following measures should be taken.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>(N/A)</p>	<p>shock, anaphylaxis, <u>or acute coronary syndrome accompanying allergic reaction</u> associated with this drug with reasonable certainty, the following measures should be taken.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><u>Acute coronary syndrome accompanying allergic reaction</u></p>
---	---

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

Pharmaceuticals and Medical Devices Agency

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