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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Cefoperazone sodium/sulbactam sodium

October 12, 2021

Therapeutic category

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

Non-proprietary name

Cefoperazone sodium/sulbactam sodium

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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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
Important Precautions 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.	Important Precautions Since no methods are currently available for predicting onset of shock, anaphylaxis, or acute coronary syndrome accompanying allergic reaction associated with this drug with reasonable certainty, the following measures should be taken.
Adverse Reactions Clinically Significant Adverse Reactions Shock, anaphylaxis (dyspnoea, etc.): Shock or anaphylaxis (dyspnoea, etc.) 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.	Adverse Reactions Clinically Significant Adverse Reactions Shock, anaphylaxis (dyspnoea, etc.), acute coronary syndrome accompanying allergic reaction: Shock, anaphylaxis (dyspnoea, etc.), or 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.

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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 of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS 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.	8. IMPORTANT PRECAUTIONS Since no methods are currently available for predicting onset of shock, anaphylaxis<u>, or acute coronary syndrome accompanying allergic reaction</u> associated with this drug with reasonable certainty, the following measures should be taken.
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Shock, anaphylaxis (dyspnoea, etc.)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Shock, anaphylaxis (dyspnoea, etc.)<u>, acute coronary syndrome accompanying allergic reaction</u>

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