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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**Tazobactam/piperacillin hydrate

February 14, 2023

## Therapeutic category

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

## Non-proprietary name

Tazobactam/piperacillin hydrate

## Safety measure

Precautions should be revised in the package insert.

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):

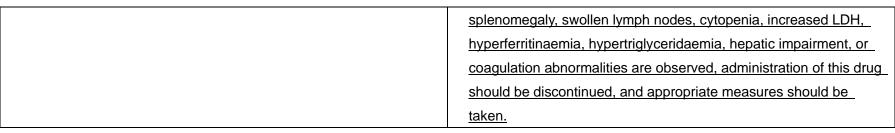
Revised language is underlined.

Current	Revision
Adverse reactions	Adverse reactions
Clinically Significant Adverse Reactions	Clinically Significant Adverse Reaction
(N/A)	Haemophagocytic lymphohistiocytosis (haemophagocytic
	syndrome):
	Haemophagocytic lymphohistiocytosis may occur. Patients should
	be carefully monitored, and if any abnormalities such as pyrexia,
	rash, neurological symptoms, splenomegaly, swollen lymph nodes,
	cytopenia, increased LDH, hyperferritinaemia,
	hypertriglyceridaemia, hepatic impairment, or coagulation
	abnormalities are observed, administration of this drug should be
	discontinued, and appropriate measures should be taken.

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

Current	Revision
11. ADVERSE REACTIONS	11. ADVERSE REACTIONS
11.1 Clinically Significant Adverse Reactions	11.1 Clinically Significant Adverse Reactions
(N/A)	Haemophagocytic lymphohistiocytosis
	(haemophagocyticsyndrome)
	If any abnormalities such as pyrexia, rash, neurological symptoms,



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