

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 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.

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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
<p>Adverse reactions Clinically Significant Adverse Reactions (N/A)</p>	<p>Adverse reactions Clinically Significant Adverse Reaction <u>Haemophagocytic lymphohistiocytosis (haemophagocytic syndrome):</u> <u>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.</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, 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
<p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)</p>	<p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Haemophagocytic lymphohistiocytosis</u> <u>(haemophagocyticsyndrome)</u> <u>If any abnormalities such as pyrexia, rash, neurological symptoms,</u></p>

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

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