



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

January 12, 2016

Non-proprietary name

Tazobactam/Piperacillin Hydrate

Safety measure

Precautions should be revised in the package insert.

In the Clinically significant adverse reaction subsection regarding toxic epidermal necrolysis (TEN) and oculomucocutaneous syndrome of the Adverse reaction section, the following text should be revised (underlined parts are revised):

Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), and acute generalised exanthematous pustulosis:

Toxic epidermal necrolysis, oculomucocutaneous syndrome, or acute generalised exanthematous pustulosis may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be adopted.

In the Clinically significant adverse reaction subsection of the Adverse reaction section, the following text should be added (underlined parts are revised):

Drug-induced hypersensitivity syndrome (DIHS)*:

Rash and/or pyrexia may occur as initial symptoms, followed by serious late-onset hypersensitivity symptoms with hepatic function disorder, lymphadenopathy, increased white blood cell count, increased eosinophil count, atypical lymphocytes, etc. Patients should be carefully monitored. If such symptoms are observed, administration of this drug should be discontinued and appropriate measures should be adopted. The reactivation of viruses including Human Herpes Virus 6 (HHV-6) has been frequently found associated with DIHS. Symptoms such as rash, pyrexia, and/or hepatic function disorder may relapse or be prolonged even after discontinuation of administration, and therefore, caution should be exercised.

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REFERENCE

Manuals for management of individual serious adverse drug reaction – Drug-induced hypersensitivity syndrome (Ministry of Health, Labour, and Welfare)

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