



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

Ampicillin hydrate

Bacampicillin hydrochloride

Ampicillin sodium/cloxacillin sodium hydrate

September 18, 2018

Non-proprietary name

Ampicillin hydrate

Bacampicillin hydrochloride

Ampicillin sodium/cloxacillin sodium hydrate

Safety measure

Precautions should be revised in the package insert.

The language concerning toxic epidermal necrolysis and oculomucocutaneous syndrome in the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section should be revised as follows (revised language is underlined):

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

Toxic epidermal necrolysis, oculomucocutaneous syndrome, or acute generalized exanthematous pustulosis may occur. Patients should be carefully monitored, and if such symptoms are observed, administration of this drug should be discontinued and appropriate measures should be taken.

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