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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

## Ampicillin hydrate/cloxacillin sodium hydrate

September 18, 2018

### **Non-proprietary name**

Ampicillin hydrate/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. If such symptoms are observed, administration of this drug should be discontinued.