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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

## Sultamicillin tosilate hydrate

September 18, 2018

### **Non-proprietary name**

Sultamicillin tosilate hydrate

### **Safety measure**

Precautions should be revised in the package insert.

The language concerning toxic epidermal necrolysis, oculomucocutaneous syndrome, and exfoliative dermatitis 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), acute generalized exanthematous pustulosis, or exfoliative dermatitis:

Toxic epidermal necrolysis, oculomucocutaneous syndrome, acute generalized exanthematous pustulosis, or exfoliative dermatitis 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.