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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

## vancomycin hydrochloride (for injection)

October 21, 2014

### Non-proprietary Name

vancomycin hydrochloride (for injection)

### Safety measure

Precautions should be revised in the package insert.

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

#### Drug-induced hypersensitivity syndrome (DIHS):

Rash and/or pyrexia may occur as the initial symptoms and signs followed by serious late-onset hypersensitivity symptoms with hepatic dysfunction, lymphadenopathy, increased white blood cells, increased eosinophilis, 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 taken. The reactivation of viruses including Human Herpes virus 6 (HHV-6) has been found frequently associated with DIHS. Symptoms such as rash, pyrexia, and/or hepatic dysfunction may relapse or be prolonged even after discontinuation of administration, and thus caution should be exercised.

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#### Reference:

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