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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 oral use)

October 21, 2014

#### **Non-proprietary Name**

vancomycin hydrochloride (for oral use)

#### **Safety measure**

Precautions should be revised in the package insert.

Information on adverse reactions reported with vancomycin hydrochloride intravenous infusion products in Clinically significant adverse reactions subsection of Adverse reactions section should be revised as follows:

Anaphylaxis, acute renal failure, interstitial nephritis, pancytopenia, agranulocytosis, thrombocytopenia, toxic epidermal necrolysis, oculomucocutaneous syndrome (Stevens-Johnson syndrome), dermatitis exfoliative, Drug-induced hypersensitivity syndrome, VIIIth cranial nerve disorders, pseudomembranous colitis, hepatic dysfunction, and/or jaundice have been reported in patients treated with vancomycin hydrochloride intravenous infusion. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be taken.

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#### Reference:

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