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, VIIth 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.

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