



Summary of investigation results

vancomycin hydrochloride

October 21, 2014

Non-proprietary Name

vancomycin hydrochloride (for Injection and oral use)

Brand Name (Marketing Authorization Holder)

- a. Vancomycin hydrochloride Intravenous Infusions 0.5 g (Shionogi & Co., Ltd) and the others
- b. Vancomycin hydrochloride Powder 0.5 g (Shionogi & Co., Ltd) and the others

Indications

- a. Vancomycin hydrochloride Intravenous Infusions 0.5 g and the others
 - Applicable microorganisms:
Vancomycin-sensitive strains of methicillin-resistant *Staphylococcus aureus* (MRSA)
Applicable conditions:
Sepsis, endocarditis infective, secondary infection (from trauma, thermal burn, surgical wound, etc.), osteomyelitis, arthritis, pneumonia, lung abscess, pyothorax, peritonitis, and pyogenic meningitis
 - Applicable microorganisms:
Vancomycin-sensitive strains of methicillin-resistant coagulase-negative staphylococci (MRCNS)
Applicable conditions:
Sepsis, endocarditis infective, secondary infection (from trauma injury, thermal burn, surgical wound, etc.), osteomyelitis, arthritis, peritonitis, and pyogenic meningitis
 - Applicable microorganisms:
Vancomycin-sensitive strains of penicillin-resistant *Streptococcus pneumoniae* (PRSP)
Applicable conditions:
Sepsis, pneumonia, and pyogenic meningitis
 - Febrile neutropenia of suspected MRSA or MRCNS



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.

- b. Vancomycin hydrochloride Powder 0.5 g and the others
 - Applicable microorganisms:
Vancomycin-susceptible strains of MRSA and *Clostridium difficile*
 - Applicable conditions:
Enteritis infectious (including pseudomembranous colitis)
 - Gastrointestinal sterilize in bone marrow transplant

Summary of revision

- a. Vancomycin hydrochloride Intravenous Infusions 0.5 g and the others
‘Drug-induced hypersensitivity syndrome’ should be added in Clinically significant adverse reactions section.
- b. Vancomycin hydrochloride Powder 0.5 g and the others
‘Drug-induced hypersensitivity syndrome’ should be added as an adverse reaction reported with vancomycin hydrochloride intravenous infusion products in Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of drug-induced hypersensitivity syndrome have been reported in patients treated with vancomycin hydrochloride intravenous infusion products in Japan. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package inserts was necessary.

The number of reported adverse reaction and fatal cases in the last 3 fiscal years in Japan

- a. Vancomycin hydrochloride Intravenous Infusions 0.5 g and the others
A total of 7 cases of drug-induced hypersensitivity syndrome has been reported (including 3 cases in which causality could not be ruled out). Of the 7 cases, no fatalities have been reported.
- b. Vancomycin hydrochloride Powder 0.5 g and the others
No drug-induced hypersensitivity syndrome has been reported.