VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP

(Full prescribing information follows)

INDICATIONS AND USAGE

Vancomycin Hydrochloride for Injection, USP is a tricyclic glycopeptide antibiotic derived from Bacillus subtilis. It is indicated for the treatment of infections caused by susceptible strains of the following microorganisms, when indicated by culture and susceptibility tests: Enterococcus faecalis (including enterococci strains resistant to ampicillin), Staphylococcus aureus (including methicillin-resistant, penicillin-resistant, and penicillin-sensitive strains), and Streptococcus pyogenes (group A beta-hemolytic streptococci) including penicillin-resistant strains.

The following in vitro data are available for Vancomycin Hydrochloride for Injection, USP, but the significance of these findings is unknown. S. aureus (including methicillin-resistant strains), Staphylococcus epidermidis and Streptococcus pyogenes (group A beta-hemolytic streptococci) are inhibited in vitro by concentrations of 1 to 4 mcg/mL.

For Staphylococcus aureus and Staphylococcus epidermidis, an in vitro minimal inhibitory concentration (MIC) of 4 mcg/mL or less is considered susceptible, 8 mcg/mL is considered intermediate, and 16 mcg/mL or greater is considered resistant. For Streptococcus pyogenes, an in vitro susceptibilities should be determined by the disk diffusion method according to the National Committee for Clinical Laboratory Standards (NCCLS).

Vancomycin is not active against Haemophilus influenzae, H. parainfluenzae, or H. arophilus. It is not active against Nocardia asteroides, N. brasiliensis, or N. farcinica. Vancomycin is not active against most strains of Proteus species, Pseudomonas aeruginosa, Acinetobacter, or Enterobacter species, or Yersinia enterocolitica. Vancomycin is not active against Bacillus anthracis, B. cereus, or B. thURINGIENSE. There is no significant overlap between the spectrum of activity of vancomycin and that of penicillin, aminoglycosides, and chloramphenicol. Vancomycin is not effective against meningococci, gonococci, or gonococcal meningitis. Vancomycin is not effective against Clostridium difficile. Although Staphylococcus aureus (MRSA) isolates resistant to oxacillin and other beta-lactams are resistant to vancomycin, clinical failures occasionally have been reported in patients with known resistance to vancomycin. These resistant strains are not easily distinguished from vancomycin-susceptible strains based on in vitro susceptibility testing. Vancomycin is not active against enterotoxigenic strains of Escherichia coli. Enterotoxigenic E. coli are inhibited in vitro by concentrations of 8 mcg/mL or less. For enterotoxigenic strains of E. coli, an in vitro minimal inhibitory concentration (MIC) of 16 mcg/mL or less is considered susceptible, 32 mcg/mL is considered intermediate, and 64 mcg/mL or greater is considered resistant.

Vancomycin is not active against Peptostreptococcus species, Listeria monocytogenes, Enterococcus faecalis, or Streptococcus bovis. However, strains of these species may be susceptible to vancomycin if they are isolated from sputum and those of Gram-negative origin are isolated from infected surgical wounds or other sites of polymicrobial infection. Vancomycin is not active against Bacteroides fragilis, Campylobacter species, Haemophilus influenzae, Pseudomonas aeruginosa, Yersinia enterocolitica, and most strains of Proteus species. Clostridium difficile is not inhibited by vancomycin.

Vancomycin is not active against enterococci strains resistant to ampicillin, enterococci strains resistant to penicillin, or group A beta-hemolytic streptococci resistant to penicillin.

Vancomycin is not active against methicillin-resistant Staphylococcus aureus. Vancomycin-resistant enterococci (VRE) are resistant to vancomycin.

Vancomycin is not effective against Enterococcus faecalis. Enterococci strains resistant to ampicillin are susceptible to vancomycin. Enterococci strains resistant to penicillin and enterococci strains resistant to both penicillin and ampicillin are resistant to vancomycin.

Vancomycin is not effective against methicillin-resistant Staphylococcus aureus. Methicillin-resistant Staphylococcus aureus is resistant to vancomycin.

Vancomycin is not effective against Enterococcus faecalis. Enterococci strains resistant to ampicillin are susceptible to vancomycin. Enterococci strains resistant to penicillin and enterococci strains resistant to both penicillin and ampicillin are resistant to vancomycin.

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Vancomycin is not effective against methicillin-resistant Staphylococcus aureus. Methicillin-resistant Staphylococcus aureus is resistant to vancomycin.