VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP

For Intravenous Use After Dilution

INDICATIONS AND USAGE

Vancomycin Hydrochloride for Injection, USP is a lyophilized powder, for preparing intravenous (IV) infusions, in bottles containing the equivalent of 5 grams or 10 grams vancomycin base. 500 mg, 1 g, 2 g, 5 g, and 10 g vancomycin hydrochloride is available in 50 mL bottles. Each mg of vancomycin contains 0.045 mg sodium. Vancomycin Hydrochloride for Injection, USP is intended for use as an adjunct to surgical antimicrobial therapy and is not a substitute for adequate surgical procedures and antimicrobial prophylaxis. Vancomycin Hydrochloride for Injection, USP has been shown to be effective alone or in combination with other antimicrobial agents in the treatment of a wide variety of serious infections caused by susceptible aerobic and anaerobic gram-positive microorganisms.

CLINICAL PHARMACOLOGY

Mechanism of Action

Vancomycin is a glycopeptide antibiotic that interferes with bacterial cell wall synthesis. Vancomycin is bactericidal in vitro and in vivo. It is bactericidal against susceptible organisms by inhibiting cell wall synthesis and causing the formation of large, non-functional, incomplete cell walls. Vancomycin binds to the transpeptidase enzyme of the bacterial cell wall synthesis apparatus, which prevents the attachment and transpeptidation of peptides that form the cross-linked peptidoglycan chains of the bacterial cell wall. This results in the inhibition of bacterial cell wall synthesis, the inhibition of bacterial growth, and the eventual death of the bacteria.

CLINICAL EXPERIENCE

The following organisms have been shown to be susceptible in vitro to vancomycin (1/100 to 1/5 minimum inhibitory concentration range): Staphylococci, including heterogeneous methicillin-resistant strains: Streptococci, including penicillin-susceptible and penicillin-resistant strains; Clostridium spp.; and Bacillus spp.

SPECIFIC DOSAGE AND ADMINISTRATION

The dosage of Vancomycin Hydrochloride for Injection, USP may be adjusted according to the severity of infection, the susceptibility of the infecting organism, the patient’s age and renal function. The usual dosage of Vancomycin Hydrochloride for Injection, USP is given by IV infusion over a period of at least 60 minutes.

10 grams Pharmacy Bulk Package Bottles

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REFERENCES