Vancomycin Hydrochloride for Injection, USP

ADA-Vantage® Vials

HOW SUPPLIED

Vancomycin Hydrochloride for Injection, USP is supplied as a sterile powder in single-dose ADA-Vantage vials that contain either 10 or 250 mg vancomycin hydrochloride. The containers are made of medical-grade glass and are sealed with aluminum caps. When reconstituted, the vials produce a solution containing 10 mg of vancomycin per milliliter. For multiple-dose containers, the reconstituted solution should be used within 24 hours, protected from light and at room temperature. For single-use vials, the reconstituted solution is stable for 48 hours, protected from light and at room temperature.

REFERENCES


ADVERSE REACTIONS

Vancomycin hydrochloride is indicated for the treatment of serious or severe infections caused by susceptible strains of methicillin-resistant Staphylococcus aureus (MRSA), methicillin-resistant Staphylococcus epidermidis, and methicillin-sensitive Staphylococcus aureus (MSSA). Common side effects associated with vancomycin include gastrointestinal disturbances, such as nausea, vomiting, and diarrhea. Other potential adverse effects include renal toxicity, which can be managed by monitoring renal function and adjusting vancomycin dosing accordingly.

CLINICAL PHARMACOLOGY

Vancomycin is a glycopeptide antibiotic that inhibits bacterial cell wall synthesis. It is strongly positive for testing the ß-lactamase enzyme. The combination of vancomycin and an aminoglycoside acts synergistically in vitro against many strains of Staphylococcus aureus, Streptococcus pneumoniae (including penicillin-resistant strains), and Streptococcus pyogenes. Vancomycin is rapidly absorbed after intravenous administration, with peak serum concentrations occurring within 1 hour. The serum creatinine must represent a steady state of renal function. Otherwise, the estimated value for creatinine clearance is not valid. Such a calculated clearance is an overestimate of actual clearance in patients with conditions: (1) characterized by hypoalbuminemia, (2) sepsis, and (3) dialysis. Serial tests of auditory function may be helpful in order to minimize the risk of ototoxicity.

Susceptibility Test Methods

A ß-lactamase test using an inoculum of about 49 mcg/mL at the completion of infusion, mean plasma concentrations of about 19 mcg/mL two hours after infusion, and mean plasma concentrations of approximately 8 mcg/mL twelve hours after the end of the infusion. Multiple dosing of 500 mg infused over 30 minutes produces mean plasma concentrations of approximately 23 mcg/mL two hours after infusion, and mean plasma concentrations of approximately 8 mcg/mL eleven hours after the end of the infusion. The mean elimination half-life of vancomycin from plasma is 4 to 6 hours in subjects with normal renal function. In the first 24 hours, vancomycin accumulates to a degree dependent on the individual's renal function. When vancomycin serum concentrations can be satisfactorily monitored, the dose should be adjusted so that peak serum concentrations are 15 to 20 mcg/mL and trough concentrations are 5 to 10 mcg/mL.

ADDITIONAL INFORMATION

Supportive care is advised, with maintenance of glomerular filtration. Vancomycin is poorly removed by dialysis. Hemofiltration and hemodialysis may be considered for patients with severe renal failure or when required for fluid management. Vancomycin is excreted in human milk. Caution should be exercised when vancomycin is administered to a nursing woman. Because CDAD has been reported to occur over two months after the administration of antibacterial agents, stool should be monitored for at least 2 weeks after treatment has been completed. The use of vancomycin should only be considered when indicated to minimize the likelihood of its widespread resistance.

PRECAUTIONS

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