125 x 200mm

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℞ Vancomycin Hydrochloride for Injection USP 1000 mg

VANCOWIN™-1000

Composition:
Each vial contains:
Vancomycin Hydrochloride (Sterile) IP
eq. to Anhydrous Vancomycin 1000mg

DESCRIPTION
Vancomycin Injection, USP in the GALAXY plastic container (PL 2040) contains vancomycin, added as Vancomycin Hydrochloride, USP. It is a tricyclic glycopeptide antibiotic drug derived from Amycolatopsis orientalis (formerly Nocardia orientalis).
The molecular formula is C66H75Cl2N9O24.HCl and the molecular weight is 1,485.71.

CLINICAL PHARMACOLOGY
In subjects with normal kidney function, multiple intravenous dosing of 1 g of vancomycin (15 mg/kg) infused over 60 minutes produces mean plasma concentrations of approximately 63 mcg/mL immediately after the completion of infusion, mean plasma concentrations of approximately 23 mcg/mL 2 hours after infusion, and mean plasma concentrations of approximately 8 mcg/mL 11 hours after the end of the infusion.
Multiple dosing of 500 mg infused over 30 minutes produces mean plasma concentrations of about 49 mcg/mL at the completion of infusion, mean plasma concentrations of about 19 mcg/mL 2 hours after infusion, and mean plasma concentrations of about 10 mcg/mL 6 hours after infusion. The plasma concentrations during multiple dosing are similar to those after a single dose.
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, about 75% of an administered dose of vancomycin is excreted in urine by glomerular filtration. Mean plasma clearance is about 0.058 L/kg/h, and mean renal clearance is about 0.048 L/kg/h. Renal dysfunction slows excretion of vancomycin. In anephric patients, the average half-life of elimination is 7.5 days. The distribution coefficient is from 0.3 to 0.43 L/kg. There is no apparent
metabolism of the drug. About 60% of an intraperitoneal dose of vancomycin administered during peritoneal dialysis is absorbed systemically in 6 hours. Serum concentrations of about 10 mcg/mL are achieved by intraperitoneal injection of 30 mg/kg of vancomycin. However, the safety and efficacy of the intraperitoneal use of vancomycin has not been established in adequate and well-controlled trials

Microbiology
The bactericidal action of vancomycin results primarily from inhibition of cell-wall biosynthesis. In addition, vancomycin alters bacterial-cell-membrane permeability and RNA synthesis. There is no cross-resistance between vancomycin and other antibiotics. Vancomycin is not active in vitro against gram-negative bacilli, mycobacteria, or fungi.
Synergy
The combination of vancomycin and an aminoglycoside acts synergistically in vitro against many strains of Staphylococcus aureus, Streptococcus bovis, enterococci, and the viridans group streptococci.

Aerobic gram-positive microorganisms
Diphtheroids
Enterococci (e.g., Enterococcus faecalis)
Staphylococci, including Staphylococcus aureus and Staphylococcus epidermidis

(including heterogeneous methicillin-resistant strains)

Streptococcus bovis
Viridans group streptococci
The following in vitro data are available, but their clinical significance is unknown. Vancomycin exhibits in vitro MIC's of 1 mcg/mL or less against most (≥90%) strains of streptococci listed below and MIC's of 4 mcg/mL or less against most (≥90%) strains of other listed microorganisms; however, the safety and effectiveness of vancomycin in treating clinical infections due to these microorganisms have not been established in adequate and well-controlled clinical trials.

Aerobic gram-positive microorganisms
Listeria monocytogenes
Streptococcus pyogenes
Streptococcus pneumoniae (including penicillin-resistant strains)
Streptococcus agalactiae

Anaerobic gram-positive microorganisms
Actinomyces species
Lactobacillus species

Susceptibility Test Methods
When available, the clinical microbiology laboratory should provide cumulative reports of in vitro susceptibility test results for antimicrobial drugs used in local hospitals and practice areas to the physician as periodic reports that describe the susceptibility profile of nosocomial and community-acquired pathogens. These reports should aid the physician in selecting the most effective antimicrobial.

INDICATIONS AND USAGE
Vancomycin is indicated for the treatment of serious or severe infections caused by susceptible strains of methicillin-resistant (beta-lactam-resistant) staphylococci. It is indicated for penicillin-allergic patients, for patients who cannot receive or who have
failed to respond to other drugs, including the penicillins or cephalosporins, and for infections caused by vancomycin-susceptible organisms that are resistant to other antimicrobial drugs.

Vancomycin is indicated for initial therapy when methicillin-resistant staphylococci are suspected, but after susceptibility data are available, therapy should be adjusted accordingly.
Vancomycin is effective in the treatment of staphylococcal endocarditis. Its effectiveness has been documented in other infections due to staphylococci, including septicemia, bone infections, lower respiratory tract infections, skin and skin structure infections. When staphylococcal infections are localized and purulent, antibiotics are used as adjuncts to appropriate surgical measures.
Vancomycin has been reported to be effective alone or in combination with an aminoglycoside for endocarditis caused by Streptococcus viridans or S. bovis. For endocarditis caused by enterococci (e.g., E. faecalis), vancomycin has been reported to be effective only in combination with an aminoglycoside. Vancomycin has been reported to be effective for the treatment of diphtheroid endocarditis. Vancomycin has been used successfully in combination with either rifampin, an aminoglycoside, or both in early-onset prosthetic valve endocarditis caused by S. epidermidis or diphtheroids.

CONTRAINDICATION
Vancomycin is contraindicated in patients with known hypersensitivity to this antibiotic. Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

WARNINGS
Rapid bolus administration (e.g., over several minutes) may be associated with exaggerated hypotension, including shock, and, rarely, cardiac arrest.

Vancomycin should be administered over a period of not less than 60 minutes to avoid rapid-infusion-related reactions. Stopping the infusion usually results in prompt cessation of these reactions.
Ototoxicity has occurred in patients receiving vancomycin. It may be transient or permanent. It has been reported mostly in patients who have been given excessive doses, who have an underlying hearing loss, or who are receiving concomitant therapy with another ototoxic agent, such as an aminoglycoside. Vancomycin should be used with caution in patients with renal insufficiency because the risk of toxicity is appreciably increased by high, prolonged blood concentrations.

Pediatric Use
In pediatric patients, it may be appropriate to confirm desired vancomycin serum concentrations. Concomitant administration of vancomycin and anesthetic agents has been associated with erythema and histamine-like flushing in pediatric patients. The potential for toxic effects in pediatric patients from chemicals that may leach from the plastic containers into the single-dose, premixed intravenous preparation has not been determined.

Geriatric Use
The natural decrement of glomerular filtration with increasing age may lead to elevated vancomycin serum concentrations if dosage is not adjusted. Vancomycin dosage schedules should be adjusted in elderly patients.

Storage: Store in a cool, dry & dark place, below 25° C. Protect from light & moisture.

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