Vancin

Infusion

DRUG INTERNATIONAL LTD.

Composition : Vancin-500 IV Infusion : Each Vial Contains Vancomycin 500mg sterile powder (As Vancomycin Hydrochloride USP).
Vancin-1gm IV Infusion : Each Vial Contains Vancomycin 1gm sterile powder (As Vancomycin Hydrochloride USP).

Pharmacology : Vancomycin is a glycopeptide antibiotic agent. The bactericidal action of vancomycin results primarily from inhibition of cell-wall biosynthesis. Vancomycin is approximately 55% serum protein bound. Vancomycin is excreted in urine by glomerular filtration.

Indications : 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.

Dosage and administration : Concentrations of up to 5mg/ml and rates of no more than 10 mg/min are recommended in adults. In selected patients in need of fluid restriction, a concentration up to 10mg/ml may be used.
Patients With Normal Renal Function : Adults : The usual daily intravenous dose is 2 g divided either as 500 mg every 6 hours or 1 g every 12 hours. Each dose should be administered at no more than 10 mg/min or over a period of at least 60 minutes, whichever is longer. Other patient factors, such as age or obesity, may call for modification of the usual intravenous daily dose. Pediatric Patients: The usual intravenous dosage of vancomycin is 10 mg/kg per dose given every 6 hours. Each dose should be administered over a period of at least 60 minutes. Close monitoring of serum concentrations of vancomycin may be warranted in these patients. Neonates: In pediatric patients up to the age of 1 month, the total daily intravenous dosage may be lower. In neonates, an initial dose of 15 mg/kg is suggested, followed by 10 mg/kg every 12 hours for neonates in the 1st week of life and every 8 hours thereafter up to the age of 1 month. Each dose should be administered over 60 minutes. In premature infants, vancomycin clearance decreases as postconceptional age decreases. Therefore, longer dosing intervals may be necessary in premature infants. Close monitoring of serum concentrations of vancomycin is recommended in these patients. Patients With Impaired Renal Function And Elderly Patients: Dosage adjustment must be made in patients with impaired renal function. In the elderly, greater dosage reductions than expected may be necessary because of decreased renal function. Measurement of vancomycin serum concentrations can be helpful in optimizing therapy, especially in seriously ill patients with changing renal function. If creatinine clearance can be measured or estimated accurately, the dosage for most patients with renal impairment can be calculated using the following table.
Dosage table for Vancomycin in patients with impaired renal function :

Creatinine Clearance ml/min	Vancomycin Dose mg/24h
100	1,545
90	1,390
80	1,235
70	1,080
60	925
50	770
40	620
30	465
20	310
10	155

The initial dose should be no less than 15 mg/kg, even in patients with mild to moderate renal insufficiency. The table is not valid for functionally anephric patients. For such patients, an initial dose of 15 mg/kg of body weight should be given to achieve prompt therapeutic serum concentrations. The dose required to maintain stable concentrations is 1.9 mg/kg/24 h. In patients with marked renal impairment, it may be more convenient to give maintenance doses of 250 to 1,000 mg once every several days rather than administering the drug on a daily basis. In anuria, a dose of 1,000 mg every 7 to 10 days has been recommended. Or, as directed by the registered physician.

Reconstitution Procedure : Vancin 500: Vancomycin 500mg injection should be reconstituted with 10ml of water for injection. The solution must be further diluted with at least 100ml of 0.9% Sodium Chloride Intravenous Infusion or 5% Glucose Intravenous Infusion or Lactated ringer's injection. The resulting solution should be infused over a period of at least 1 hour.
Vancin 1gm: Vancomycin 1gm injection should be reconstituted with 20ml of water for injection. The solution must be further diluted with at least 200ml of 0.9% Sodium Chloride Intravenous Infusion or 5% Glucose Intravenous Infusion or Lactated ringer's injection. The resulting solution should be infused over a period of at least 2 hours.

Contraindication : Vancomycin is contraindicated in patients with known hypersensitivity to Vancomycin or any other components of this product.

Precautions : Prolonged use of vancomycin may result in the overgrowth of nonsusceptible microorganisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken. In rare instances, there have been reports of pseudomembranous colitis due to C. difficile developing in patients who received intravenous vancomycin. Vancomycin is irritating to tissue and must be given by a secure intravenous route of administration. Pain, tenderness, and necrosis occur with inadvertent extravasation. Thrombophlebitis may occur, the frequency and severity of which can be minimized by slow infusion of the drug and by rotation of venous access sites.

Side effects : During or soon after rapid infusion of vancomycin, patients may develop anaphylactic reactions, including hypotension, wheezing, dyspnea, urticaria, or pruritus. Rapid infusion may also cause flushing of the upper body (red neck) or pain and muscle spasm of the chest and back. These reactions usually resolve within 20 minutes but may persist for several hours. Such events are infrequent if vancomycin is given by a slow infusion over 60 minutes.

Use in pregnancy and lactation : Pregnancy Category C. It is not known whether vancomycin causes fetal harm. Vancomycin should be given to a pregnant woman only if clearly needed. Vancomycin is excreted in human milk. Caution should be exercised when vancomycin is administered to a nursing woman. Because of the potential for adverse events, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Use in Child : See dosage and administration.

Drug interactions : Concomitant administration of vancomycin and anesthetic agents has been associated with erythema and histamine-like flushing and anaphylactoid reactions. Precaution should be taken during concurrent or sequential use of other potentially neurotoxic or nephrotoxic drugs, such as amphotericin B, aminoglycosides, bacitracin, polymyxin B, colistin, viomycin, or cisplatin.

Overdose : Supportive care is advised, with maintenance of glomerular filtration. Vancomycin is poorly removed by dialysis.

Storage : Store below 30°C in a dry place.

Packing : Vancin-500 IV Infusion : Each box Contains 1 vial of Vancomycin 500mg sterile powder (As Vancomycin Hydrochloride USP).
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