Vancomin®

Vancomycin

Description
Vancomycin is a glycopeptide antibiotic derived from *Nocardia orientalis* (formerly *Streptomyces orientalis*) and is active against many Gram-positive bacteria including *Staphylococcus aureus*, *Staph. epidermidis*, alpha and beta haemolytic streptococci, group D. streptococci, corynebacteria and clostridia.

Composition
Vancomin® 250 mg Capsule: Each capsule contains vancomycin Hydrochloride USP 256.3 mg equivalent to Vancomycin 250 mg.
Vancomin® 500 mg IV Infusion: Each vial contains Sterile Vancomycin Hydrochloride USP equivalent to Vancomycin 500 mg.
Vancomin® 1 gm IV Infusion: Each vial contains Sterile Vancomycin Hydrochloride USP equivalent to Vancomycin 1 gm.

Indications
***Oral:* Capsule:** Indicated in adults (≥18 years) and pediatric patients (<18 years) for the treatment of: *Clostridium difficile* associated diarrhea, Enterocolitis caused by *Staphylococcus aureus* (including methicillin resistant strains).
Parenteral administration of vancomycin is not effective for the above infections; therefore, capsule & oral solution must be given orally for these infections.Vancomycin is indicated in potentially life-threatening infections which cannot be treated with other effective, less toxic antimicrobial drugs including the penicillins and cephalosporins.
Infusion: Vancomycin is useful in the therapy of severe staphylococcal infections in patients who cannot receive or who have failed to respond to the penicillins and cephalosporins or who have infections with staphylococci, resistant to other antibiotics.
Vancomycin is used in the treatment of endocarditis and as prophylaxis against endocarditis in patients undergoing dental or surgical procedures.
Its effectiveness has been documented in other infections due to staphylococci including osteomyelitis, pneumonia, septicemia and soft tissue infections.

Dosage and administration
Capsule
Clostridium difficile associated diarrhea: Adult Patients (≥18 years): 125 mg orally 4 times daily for 10 days.
Pediatric Patients (<18 years): 40 mg/kg in 3 or 4 divided doses for 7 to 10 days. The total daily dosage should not exceed 2 gm.
Staphylococcal enterocolitis: Adult Patients (≥18 years): 500 mg to 2 gm orally in 3 or 4 divided doses for 7 to 10 days.
Pediatric Patients (<18 years): 40 mg/kg in 3 or 4 divided doses for 7 to 10 days. The total daily dosage should not exceed 2 g.
Infusion: Infusion related events are related to both concentration and rate of administration of Vancomycin. Concentrations of no more than 5 mg/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 10 mg/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.
Children: 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.
Infants and Neonates: In pediatric patients up to the age of 1 month, the total daily intravenous dosage may be lower. In both neonates and
infants, 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.
Patients with Impaired Renal Function and Elderly Patients: Dosage adjustment must be made in patients with impaired renal function. In premature infants and the elderly, greater dosage reductions than expected may be necessary because of decreased 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/24 h
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 in order 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 dose of 250 to 1,000 mg once every several days rather than administrating the drug on a daily basis. In anuria, a dose of 1,000 mg every 7-10 days has been recommended.
Intermittent infusion is the recommended method of administration.

Method of reconstitution
At the time of use, reconstitute by adding either 10 ml of sterile water for injection to the 500 mg vial or 20 ml of sterile water for injection to the 1 g vial of dry, sterile Vancomycin powder. Vials reconstituted in this manner will give a solution of 50 mg/ml. Further dilution is required.
Reconstituted solutions containing 500 mg of Vancomycin must be diluted with at least 100 ml of diluent. Reconstituted solutions containing 1 g of Vancomycin must be diluted with at least 200 ml of diluent. The desired dose, diluted in this manner, should be administered by intermittent IV infusion over a period of at least 60 minutes.
The following diluents are physically and chemically compatible: 5% dextrose injection, 5% dextrose and 0.9% Sodium Chloride injection, Lactated Ringer's injection, 5% dextrose and Lactated Ringer's injection, Normosol-M and 5% dextrose, 0.9% Sodium Chloride injection, Isolyte E, and Acetated Ringer's injection.

Contraindication
Vancomycin is contraindicated in patients with known hypersensitivity to this antibiotic.

Side effects
Vancomycin is well tolerated. However during or soon after rapid infusion of Vancomycin, patients may develop anaphylactic reactions including hypotension, wheezing, dyspnoea, 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
Vancomycin Hydrochloride is excreted in human milk. Caution should be exercised when Vancomycin is administered to a nursing woman. It is unlikely that a nursing infant can absorb a significant amount of Vancomycin from its gastro-intestinal tract.

Precautions
Patients with borderline renal function and individuals over the age of 60 should be given serial tests of auditory function and of Vancomycin blood levels. All patients receiving the drug should have periodic haematological studies, urine analysis and renal function tests.
Vancomycin is very irritating to tissue and causes injection site necrosis when injected intramuscularly. It must be infused intravenously. Injection site pain and thrombophlebitis occur in many patients receiving Vancomycin and are occasionally severe.
Prolonged use of Vancomycin may result in the overgrowth of non-susceptible organisms. 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.

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

Over dosage
Supportive care is advised with maintenance of glomerular filtration. Vancomycin is poorly removed from the blood by haemodialysis or peritoneal dialysis. Haemoperfusion with Amberlite resin XAD-4 has been reported to be of limited benefit.

Storage
Keep out of reach of children. Store in a dry place, below 25˚C temperature and protected from light.

Packaging
Vancomin® 250 mg Capsule: Each carton contains 6X2 capsules in blister pack.
Vancomin® 500 mg IV Infusion: Each carton contains 1 vial of Sterile Vancomycin Hydrochloride USP equivalent to Vancomycin 500 mg, 1 vial of diluent (100 ml 0.9% w/v NaCl) & plastic hanger.
Vancomin® 1 gm IV Infusion: Each carton contains 1 vial of Sterile Vancomycin Hydrochloride USP equivalent to Vancomycin 1 gm, 1 vial of diluent (200 ml 0.9% w/v NaCl) & plastic hanger.

Opsonin Pharma
Ideas for healthcare

Manufactured by
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