

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

VANCOGIN[®] CP

Vancomycin Hydrochloride for Injection USP

Indications:

VANCOGIN[®] CP is a chromatographically purified, tricyclic glycopeptide antibiotic indicated for initial therapy in the treatment of serious or severe infections caused by susceptible strains of methicillin-resistant (beta-lactam-resistant) staphylococci, such as endocarditis, septicemia, bone and joint infections, lower respiratory tract infections, and skin and skin structure infections. It is useful alone or in combination with an aminoglycoside for endocarditis caused by *Streptococcus viridans* or *Streptococcus bovis*. For endocarditis caused by Enterococci (eg, *Enterococcus faecalis*), it is effective only in combination with an aminoglycoside. It is successfully used in combination with either rifampin or an aminoglycoside, or both in early-onset prosthetic valve endocarditis caused by *Staphylococcus epidermidis* or diphtheroids.

The parenteral form may be administered orally for treatment of antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile* and for Staphylococcal enterocolitis. Parenteral administration of Vancomycin alone is of unproven benefit for these indications. **VANCOGIN[®] CP is not effective by the oral route for other types of infection.**

It is also indicated for penicillin-allergic patients.

Dosage and Method of Administration:

Adults - IV 2 g divided either as 500 mg every 6 hours or 1 g every 12 hours. Each dose administered at no more than 10 mg/min or over a period of at least 60 minutes, whichever is longer.

Pediatric Patients - IV mg/kg per dose given every 6 hours. Each dose administered over a period of at least 60 minutes.

Infants And Neonates - initial dose of 15 mg/Kg followed by 10mg/Kg every 12 hours in the first week of life, and every 8 hours thereafter up to the age of one month. Each dose should be administered over at least 60 minutes. (Refer to full prescribing information)

Renal impairment and Elderly patients – Reduce dosage if creatinine clearance is < 100 ml/min. The initial dose should be no less than 15 mg/kg, even in patients with mild to moderate renal insufficiency. (Refer to full prescribing information)

Intermittent infusion is the recommended method of administration.

Contraindications:

Contraindicated in patients with known hypersensitivity to the product.

Warnings and Precautions:

Warnings: Rapid bolus administration associated with exaggerated hypotension, and, rarely, cardiac arrest. Transient or permanent ototoxicity noted in patients receiving Vancomycin. Used with caution in patients with renal insufficiency. Administered with caution in patients allergic to teicoplanin due to known allergic cross reactions between Vancomycin and teicoplanin.

Precautions:

- **General** : Monitor renal function to minimize the risk of nephrotoxicity in patients with renal dysfunction or patients receiving concomitant aminoglycoside therapy. Monitor auditory function to minimize the risk of ototoxicity.
- **Renal Insufficiency** : Used with caution in patients with renal function insufficiency because the risk of toxicity may be appreciably increased by high, prolonged blood concentrations.
- **Use In Pediatrics** : In premature neonates and young infants, it may be appropriate to confirm desired Vancomycin serum concentrations.
- **Geriatrics** : Vancomycin dosage schedules should be adjusted in elderly patients.

Interactions:

Co-administration of anesthetic agents associated with erythema and histamine-like flushing and anaphylactoid reactions. Concurrent and/or sequential systemic or topical use of potentially neurotoxic and/or nephrotoxic drugs, such as amphotericin B, aminoglycosides, bacitracin, polymyxin B, colistin, viomycin, or cisplatin, requires careful monitoring.

Pregnancy and Lactation:

The safety of Vancomycin for use in human pregnancy has not been established. Vancomycin HCl should be given to a pregnant woman only if clearly needed.

Adverse Effects:

Rapid infusion may cause nausea, pseudomembranous colitis, hematologic reactions, interstitial nephritis, renal failure, exfoliate dermatitis, hypersensitivity reactions, linear IgA bullous dermatosis, pruritis, rash, 'Red Man' syndrome, toxic epidemal necrolysis, urticaria, vasculitis, hearing loss and ototoxicity, chills, drug fever, injection site necrosis, injection site pain, thrombophlebitis. Vertigo, dizziness, and tinnitus have rarely been reported. Reversible neutropenia noted with higher doses.

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(For sale in India and Nepal only)**

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Consult full prescribing information before prescribing. Further information is available on request from:
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