Vancom

(Vancomycin HCl)
For Injection U.S.P.

FOR I.V. USE ONLY
500mg
1g

وینکوم
انجکشن ۵۰۰ ملی گرام
۱ گرام

DESCRIPTION:
Vancom is brand name of Vancomycin HCl U.S.P. for I.V. use only.

QUALITATIVE AND QUANTITATIVE COMPOSITION:
Vancom For Injection U.S.P. 500mg
Each vial contains:
Vancomycin Hydrochloride U.S.P. eq. to
Vancomycin 500mg
Vancom For Injection U.S.P. 1g
Each vial contains:
Vancomycin Hydrochloride U.S.P. eq. to
Vancomycin 1g

CLINICAL PHARMACOLOGY:
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.
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. Vancomycin has been shown to be active against most strains of the following microorganisms, both in vitro and in clinical infections which are as follows
Aerobic gram-positive microorganisms
- *Listeria monocytogenes*
- *Streptococcus pyogenes*
- *Streptococcus pneumoniae (including penicillin-resistant strains)*
- *Streptococcus agalactiae*

Anaerobic gram-positive microorganisms
- *Actinomyces species,*
- *Lactobacillus species*

INDICATIONS AND USAGE:
Vancom(Vancomycin HCl) 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 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.Vancomycin has been reported to be effective alone or in combination with an aminoglycoside for endocarditis caused by *Streptococcus* viridans or S. bovis.

CONTRAINDICATIONS:
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.

PRECAUTIONS:
General: Prolong 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.
Drug Interactions: Concomitant administration of vancomycin and anesthetic agents has been associated with erythema and histamine-like flushing and anaphylactoid reactions.
Pregnancy:
• Teratogenic Effects • Pregnancy Category C
Nursing Mothers: Vancomycin is excreted in human milk. Caution should be exercised when vancomycin is administered to a nursing woman.
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.

ADVERSE REACTIONS:
Infusion-Related Events: During or soon after rapid infusion of vancomycin, patients may develop anaphylactoid 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. In studies of normal volunteers, infusion-related events did not occur when vancomycin was administered at a rate of 10 mg/min or less.
Nephrotoxicity: Renal failure, principally manifested by increased serum creatinine or BUN concentrations, especially in patients administered large doses of vancomycin, has been reported rarely. Cases of interstitial nephritis have also been reported rarely. Most of these have occurred in patients who were given aminoglycosides concomitantly or who had preexisting kidney dysfunction. When vancomycin was discontinued, azotemia resolved in most patients.
Gastrointestinal: Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment Ototoxicity: A few dozen cases of hearing loss associated with vancomycin have been reported. Most of these patients had kidney dysfunction or a preexisting hearing loss or were receiving concomitant treatment with an ototoxic drug. Vertigo, dizziness, and tinnitus have been reported rarely.
Hematopoietic: Reversible neutropenia, usually starting 1 week or more after onset of therapy with vancomycin or after a total dosage of more than 25 g, has been reported for several dozen patients. Neutropenia appears to be promptly reversible when vancomycin is discontinued. Thrombocytopenia has rarely been reported. Although a causal relationship has not been established, reversible agranulocytosis (granulocytes <500/mm superscript 3) has been reported rarely.
Phlebitis Inflammation at the injection site has been reported.

DOSAGE AND ADMINISTRATION:
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. For bacterial endocarditis, the generally accepted regimen is 1 g vancomycin intravenously every 12 hours for 4 weeks either alone or in combination with other antibiotics. Longer treatment up to 6 weeks may be required, depending on the pathogen involved. National guidelines should be adhered to. If Vancomycin is co-administrated with an aminoglycoside (e.a. gentamycine) patients should be monitored carefully for signs of neurotoxicity and ototoxicity. The dosage should be adjusted when renal disturbance occurs. Peri-operative prophylaxis against bacterial endocarditis: Adults receive 1g vancomycin intravenously prior to surgery (prior to induction of anaesthesia) and depending on time and type of surgery, the dose of 1g of vancomycin i.v. 12 hours postoperatively can be given.
Children: 40mg/kg/day (10mg/kg every 6hours) of body weight or as directed by the physician.
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.
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.

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.

INSTRUCTIONS FOR RECONSTITUTION:
The powder must be reconstituted and the resulting concentrate must then be immediately diluted further prior to use.
Dissolve the content of each 500mg in 10mL and 1 g vial in 20ml of sterile water for injections. One ml of reconstituted solution contains 50mg of vancomycin. Clear colourless to pale yellow solution free from fibre and visible particulate matters
Intermittent infusion:
If further reconstitution is required, intermittent infusion is the preferred method of administration. Reconstituted solution containing 500mg can be added to 100ml to 200ml and 1 g vancomycin (50mg/ml) must be diluted further with at least 200ml of either 0.9% sodium chloride or 5% glucose in sterile water for injection.
The desired dose should be administered slowly by intravenous infusion at a rate of no more than 10mg/minute, for at least 60 minutes or even longer. Before administration, the reconstituted and diluted solutions should be inspected visually for particulate matter and discoloration. Only clear and colourless to pale yellow solution free from particles should be used. Vials are for single use only. Unused product must be discarded. Any unused product or waste material should be disposed of in accordance with local requirements.

INSTRUCTIONS:
Must be diluted before use. Keep all medicines out of the reach of children. To be sold on the prescription of a registered medical practitioner only.
Storage: Before reconstitution: Store at 20°C to 25°C, excursions permitted to 15°C - 30°C. Protect from sunlight and moisture.
After reconstitution: Preferably used immediately or must be stored in refrigerator for 24 hours only if necessary.

PRESENTATION:
Vancom (Vancomycin HCl) For Injection U.S.P. 500mg is available in pack of 1 Vial + 10mL water for Injection with Leaflet.
Vancom (Vancomycin HCl) For Injection U.S.P. 1g is available in pack of 1 Vial + 2x10mL water for Injection with Leaflet.

وینکوم سلوشن بنانے کے لئے:
۵۰۰ ملی گرام بنانے کے لئے ۱۰ ملی لیٹر واٹر فار انجکشن وائل میں ڈالیں۔
۱ گرام بنانے کے لئے ۲۰ ملی لیٹر واٹر فار انجکشن وائل میں ڈالیں۔
بڑوں کے لئے: ۱ گرام ہر ۱۲ گھنٹے بعد یا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
بچوں کے لئے: ۴۰ ملی گرام / کلوگرام / یومیہ (۱۰ ملی گرام / کلوگرام / ۶ گھنٹے) یا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
انجکشن کے ایک بھلوں کے دھندلا ہونے یا کسی بھی قسم کی غیر حل پذیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔
ہدایات:
استعمال سے پہلے سلوشن ضرور بنائیں۔
سلوشن بنانے سے پہلے: ۲۰ سے ۲۵ ڈگری سینٹی گریڈ پر رکھیں، محفوظ رکھنے کی حد ۱۵ سے ۳۰ ڈگری سینٹی گریڈ ہے۔
سورج کی روشنی اور نمی سے محفوظ رکھیں۔
سلوشن بنانے کے بعد: تیار شدہ سلوشن فوراً استعمال کرلیں یا اگر ضروری تو ۲۴ گھنٹے کے لئے ریفریجریٹر میں رکھا جا سکتا ہے۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔ صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کریں۔

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