Vinjec® CP Injection

(V a n c o m y c i n H C l)

Sterile Lyophilized powder

وینجیک انجکشن

(وینکومائیسین ہائیڈروکلورائیڈ)

DESCRIPTION:
Vancomycin is a tricyclic glycopeptide antibiotic derived from *Amycolatopsis orientalis* (formerly *Nocardia orientalis*). The chemical name for vancomycin hydrochloride is 3S [3R*,6S*(S*),7S*,22S*,23R*,26R*,36S*,38aS*]]-3-(2-Amino-2-oxoethyl)-44-[[2-O-(3-amino2, 3,6-trideoxy-3-C-methyl-α-L-lyxo-hexopyranosyl)-ß-D-glucopyranosyl]oxy]-10, 19-dichloro2, 3, 4, 5, 6, 7, 23, 24, 25, 26,36, 37, 38, 38a-tetradecahydro-7,22,28,30,32-pentahydroxy-6-[[4-methyl2-(methylamino)-1-oxopentyl]amino]-2,5,24,38,39-pentaoxo-22H-8,11:18,21-dietheno-23,36(iminomethano)-13, 16:31,35-dimetheno-1H,16H-[1,6,9]oxadiazacyclohexadecino[4,5¬m][10,2,16]-benzoxadiazacyclotetracosine-26-carboxylic acid, monohydrochloride. The molecular formula is $C_{66}H_{75}Cl_2N_9O_{24}$• HCl and the molecular weight is 1,485.74.

COMPOSITION:
Each Vinjec 500mg vial contains:
Vancomycin .... 500mg as Vancomycin Hydrochloride U.S.P.
(Product Specs.: U.S.P.)

Each Vinjec 1000mg vial contains:
Vancomycin .... 1000mg as Vancomycin Hydrochloride U.S.P.
(Product Specs.: U.S.P.)

CLINICAL PHARMACOLOGY:
Pharmacodynamic Properties:
Pharmacotherapeutic group: glycopeptide antibacterial, ATC Code: J01 XA01.

Mechanism of Action:
Vancomycin is a tricyclic glycopeptide antibiotic that inhibits the synthesis of the cell wall in sensitive bacteria by binding with high affinity to the D-alanyl-D-alanine terminus of cell wall precursor units. The drug is slowly bactericidal for dividing microorganisms. In addition, it impairs the permeability of the bacterial cell membrane and RNA synthesis.

THERAPEUTIC INDICATIONS:
Vancomycin is indicated in all age groups for the treatment of the following infections:
- complicated skin and soft tissue infections (cSSTI)
- bone and joint infections
- community acquired pneumonia (CAP)
- hospital acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP)
- infective endocarditis

Vancomycin is also indicated in all age groups for the perioperative antibacterial prophylaxis in patients that are at high risk of developing bacterial endocarditis when undergoing major surgical procedures.

DOSAGE AND ADMINISTRATION:
Patients aged 12 Years and older:
The recommended dose is 15 to 20 mg/kg of body weight every 8 to 12 h (not to exceed 2 g per dose). In seriously ill patients, a loading dose of 25–30 mg/kg of body weight can be used to facilitate rapid attainment of target trough serum vancomycin concentration.

Infants and Children (1 Month to less than 12 Years Of Age):
The recommended dose is 10 to 15 mg/kg body weight every 6 hours

PMA: Post-menstrual age [time elapsed between the first day of the last menstrual period and birth (gestational age) plus the time elapsed after birth (post-natal age)].

PMA (weeks)	Dose (mg/kg)	Interval of administration (h)
<29	15	24
29-35	15	12
>35	15	8

Elderly:
Lower maintenance doses may be required due to the age-related reduction in renal function.

Adults
The usual starting dose for adult patients is 15 to 20 mg/kg that could be administered every 24 hours in patients with creatinine clearance between 20 to 49 mL/min. In patients with severe renal impairment (creatinine clearance below 20 mL/min) or those on renal replacement therapy. In the critically ill patient with renal insufficiency, the initial loading dose (25 to 30 mg/kg) should not be reduced.

Paediatrics
Dose adjustments in paediatric patients aged 1 year and older could be based on glomerular filtration rate.

GFR (mL/min/1.73 m²)	IV dose	Frequency
50-30	15 mg/kg	12 hourly
29-10	15 mg/kg	24 hourly
< 10		Re-dose based on levels*
Intermittent haemodialysis	10-15 mg/kg	
Peritoneal dialysis		
Continuous renal replacement therapy	15 mg/kg	Re-dose based on levels*

Method of Administration:
Intravenous vancomycin is usually administered as an intermittent infusion or Vancomycin shall only be administered as slow intravenous infusion of at least one hour duration or at a maximum rate of 10 mg/min (whichever is longer) which is sufficiently diluted (at least 100 mL per 500 mg or at least 200 mL per 1000 mg)

RECONSTITUTION:
At the time of use, reconstitute the vials of Vinjec® (Vancomycin Hydrochloride) with Sterile Water for Injection to a concentration of 50 mg of vancomycin/mL

Concentration / Vial	Volume of diluent
500 mg	10 ml
1 g	20 ml

After reconstitution, the vials may be stored in a refrigerator for 14 days without significant loss of potency. Reconstituted solutions of vancomycin (500 mg/10 mL) must be further diluted in at least 100 mL of a suitable infusion solution. For doses of 1 gram (20 mL), at least 200 mL of solution must be used. The desired dose diluted in this manner should be administered by intermittent IV infusion over a period of at least 60 minutes.

CONTRAINDICATIONS:
Vancomycin hydrochloride for injection is contraindicated in patients with known hypersensitivity to this antibiotic.

WARNINGS AND PRECAUTIONS:
Hypersensitivity reactions
Serious and occasionally fatal hypersensitivity reactions are possible. In case of hypersensitivity reactions, treatment with vancomycin must be discontinued immediately and the adequate emergency measures must be initiated.

Ototoxicity
Ototoxicity, which may be transitory or permanent has been reported in patients with prior deafness, who have received excessive intravenous doses, or who receive concomitant treatment with another ototoxic active substance such as an aminoglycoside. Vancomycin should also be avoided in patients with previous hearing loss. Deafness may be preceded by tinnitus. To reduce the risk of ototoxicity, blood levels should be determined periodically and periodic testing of auditory function is recommended.

Infusion-related reactions
Rapid bolus administration (i.e. over several minutes) may be associated with exaggerated hypotension (including shock and, rarely, cardiac arrest), histamine like responses and maculopapular or erythematous rash ("red man's syndrome" or "red neck syndrome"). Vancomycin should be infused slowly in a dilute solution (2.5 to 5.0 mg/mL) at a rate no greater than 10 mg/min and over a period not less than 60 minutes to avoid rapid infusion-related reactions. Stopping the infusion usually results in a prompt cessation of these reactions.

Severe cutaneous adverse reactions (SCARs)
Severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported in association with vancomycin treatment.

Nephrotoxicity
Vancomycin should be used with care in patients with renal insufficiency, including anuria, as the possibility of developing toxic effects is much higher in the presence of prolonged high blood concentrations. The risk of toxicity is increased by high blood concentrations or prolonged therapy.

Eye disorders
Vancomycin is not authorized for intracameral or intravitreal use, including prophylaxis of endophthalmitis. Hemorrhagic occlusive retinal vasculitis (HORV), including permanent loss of vision, have been observed in individual cases following intracameral or intravitreal use of vancomycin during or after cataract surgery.

DRUG INTERACTIONS:
Concomitant administration of vancomycin and anaesthetic agents has been associated with erythema, histamine-like flushing and anaphylactoid reactions.

Concurrent or sequential systemic or topical use of other potentially ototoxic or nephrotoxic drugs, such as amphotericin B, aminoglycosides, bacitracin, polymixin B, colistin, viomycin, cisplatin, loop diuretics, piperacillin/tazobactam and NSAIDs may increase the toxicity of vancomycin and if they need to be given should be used with caution and appropriate monitoring.

ADVERSE EFFECTS:
Common:
Decrease in blood pressure, Dyspnea, stridor, Flushing of the upper body ("red man syndrome"), exanthema and mucosal inflammation, pruritus, urticaria, Renal insufficiency manifested primarily by increased serum creatinine and serum urea, Phlebitis, redness of the upper body and face.

Uncommon:
Transient or permanent loss of hearing

Rare:
Reversible neutropenia, agranulocytosis, eosinophilia, thrombocytopenia, pancytopenia, Hypersensitivity reactions, anaphylactic reactions, Vertigo, tinnitus, dizziness, Vasculitis, Nausea, Interstitial nephritis, acute renal failure, Drug fever, shivering, Pain and muscle spasm of the chest and back muscles

Very Rare:
Cardiac arrest, Pseudomembranous enterocolitis, Exfoliative dermatitis, Stevens-Johnson syndrome, Toxic epidermal necrolysis (TEN), Linear IgA bullous dermatosis.
Not Known:
Vomiting, Diarrhea, Eosinophilia, and systemic symptoms (DRESS syndrome), AGEP (Acute Generalized Exanthematous Pustulosis), Acute tubular necrosis

USE IN PREGNANCY AND LACTATION:
Pregnancy:
It is not known whether it causes foetal harm. Vancomycin should be given in pregnancy only if clearly needed and blood levels should be monitored carefully to minimise the risk of foetal toxicity.

Lactation:
Vancomycin hydrochloride is excreted in human milk. Caution should be exercised when vancomycin is administered to a nursing woman.

OVERDOSE:
Supportive care is advised, with maintenance of glomerular filtration. Vancomycin is poorly removed by dialysis. Hemofiltration and hemoperfusion with polysulfone resin have been reported to result in increased vancomycin clearance.

COMPATIBILITIES:
Solutions that are diluted with 5% Dextrose Injection or 0.9% Sodium Chloride Injection may be stored in a refrigerator for 14 days without significant loss of potency. Solutions that are diluted with the following infusion fluids may be stored in a refrigerator for 96 hours:
- 5% Dextrose Injection and 0.9% Sodium Chloride Injection USP
- Lactated Ringer's Injection USP
- Lactated Ringer's and 5% Dextrose Injection USP
- Normosol®-M and 5% Dextrose
- Isolyte® E
- Acetated Ringer's Injection

INCOMPATIBILITIES:
Vancomycin solution has a low pH that may cause chemical or physical instability when it is mixed with other compounds.

SHELF LIFE: 3 years

STORAGE:
Protect from heat, sunlight & moisture,
store between 15°C - 30°C.
The expiration date refer to the product correctly stored at the required condition.
Precautions: Keep out of the reach of children.
Do not use if a clear solution is not obtained even after vigorous shaking.
Patients and healthcare professionals can also report suspected adverse drug reaction at ade@bosch-pharma.com.
To be sold on prescription of a registered medical practitioner only.

PRESENTATION:
Vinjec 500mg Injection: Pack of 1 vial + 1 Ampoule of 10ml Sterile Water for injection as solvent .
Vinjec 1000mg Injection: Pack of 1 vial + 2 Ampoules of 10ml Sterile Water for injection as solvent .

صرف وریدی استعمال کے لئے۔
خوراک: ڈاکٹری ہدایت کے مطابق استعمال کریں۔
ہدایات:۔
دھوپ، گرمی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔
بچوں کی پہنچ سے دُور رکھیں۔
احتیاط: انجکشن میں کوئی غیر مل پریشے نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔
صرف مستند ڈاکٹر کے نسخے پر فروخت کے لئے۔

Manufactured by:
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ISO 9001:2015 Certified Company