VANBACT I.V. Injection for Infusion وینبیکٹ آئی-وی

(VANCOMYCIN HCl INJECTION USP) (وینکومائسین ہائیڈروکلورائیڈ) انجکشن برائے انفیوژن

Chromatographically Purified

CP

COMPOSITION:

VANBACT 500mg I.V. Injection:
Each vial of lyophilized powder contains:
Vancomycin HCl USP equivalent to Vancomycin .... 500mg. [USP Specs.]

VANBACT 1g I.V. Injection:
Each vial of lyophilized powder contains:
Vancomycin HCl USP equivalent to Vancomycin ..... 1g. [USP Specs.]

INDICATIONS AND USAGE:
Vancomycin HCl is indicated for the treatment of serious or severe infections caused by susceptible strains of Methicillin Resistant (β-lactam resistant) Staphylococci. It is indicated for penicillin-allergic 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 HCl is indicated for initial therapy when Methicillin Resistant Staphylococci are suspected but after susceptibility data are available, therapy should be adjusted accordingly. Vancomycin HCl is effective in the treatment of Staphylococcal endocarditis. Its effectiveness has been documented in other infections caused by Staphylococci including septicemia, bone infections, lower respiratory tract infections and skin and skin structure infections.

CONTRA-INDICATIONS: Known hypersensitivity to Vancomycin HCl.

WARNINGS:
Rapid bolus administration (e.g. over several minutes) may be associated with exaggerated hypotension and rarely cardiac arrest. Vancomycin HCl should be administered in a diluted solution over a period of not less than 60 minutes to avoid rapid-infusion related reactions. Dosage of Vancomycin HCl must be adjusted for patients with renal dysfunction.

PRECAUTIONS:
Renal dysfunction: In patients with underlying renal dysfunction, serial monitoring of renal function should be performed.
Pregnancy: It is not known whether Vancomycin HCl can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Vancomycin HCl should be given to a pregnant woman only if clearly needed.
Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Vancomycin HCl is administered to a nursing woman.

ADVERSE REACTIONS:
Anaphylactoid reactions including hypotension, wheezing, dyspnea, urticaria, 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 HCl is given by a slow infusion over a period of 60 minutes. Abnormal renal function tests, ototoxicity, neutropenia, thrombocytopenia, inflammation at the injection site and thrombophlebitis may also occur.

DOSAGE AND ADMINISTRATION:
Patients with Normal Renal Function:
Adults: The usual daily intravenous dose is 2g divided either as 500mg every 6 hours or 1g every 12 hours. Each dose should be administered over a period of at least 60 minutes. Other patient factors such as age or obesity may call for modification of the usual daily dose.
Children: The total daily intravenous dosage of Vancomycin HCl, calculated on the basis of 40mg/kg of body weight, can be divided and incorporated into the child's 24 hours fluid requirement. Each dose should be administered over a period of at least 60 minutes.
Infants and Neonates: In neonates and young infants, the total daily intravenous dosage may be lower. In both neonates and infants; an initial dose of 15mg/kg is suggested, followed by 10mg/kg every 12 hours for neonates in the first week of life and every 8 hours there after upto the age of 1 month. Close monitoring of serum concentrations of Vancomycin HCl may be warranted in these patients.

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The safety and efficacy of Vancomycin HCl administration by the intrathecal (intralumbar or intraventricular) route have not been assessed.
Patients with impaired Renal function and elderly patients: Dosage adjustment must be made in patients with impaired renal function. In the elderly, dosage reduction may be necessary to a greater extent than expected because of decreasing renal function.
Measurement of Vancomycin serum concentration can be helpful in optimizing therapy, especially in seriously ill patients with changing renal function. Vancomycin serum concentration can be determined by use of microbiological assay, radioimmunoassay, fluorescence polarization immunoassay, fluorescence immunoassay or high pressure liquid chromatography.
The dosage of Vancomycin HCl per day in mg is about 15 times the glomerular filtration rate in ml/min. The initial dose should be not less than 15mg/kg, even in patients with mild to moderate renal insufficiency. For functionally anephric patients, an initial dose of 15mg/kg of body weight should be given in order to achieve prompt therapeutic serum concentrations. The dose required to maintain stable concentrations is 1.9mg/kg/24 hours. Since individual maintenance dose of 250 to 1,000mg is convenient, 1 dose may be given every several days rather than on a daily basis, in patients with marked renal impairment, in anuria, a dose of 1,000mg every 7 to 10 days has been recommended. Intermittent infusion is the recommended method of administration. Intraperitoneal administration is not recommended.

PREPARATION AND STABILITY:
At the time of use, reconstitute by adding either 10ml of Sterile water for injection to the 500mg vial or 20ml of Sterile water for injection to the 1g vial of dry sterile Vancomycin HCl powder.
Further Dilution: After reconstitution, the vial may be stored in a refrigerator for 14 days without significant loss of potency. Reconstituted solution containing 500mg of Vancomycin must be diluted with at least 100ml of diluent. Reconstituted solution containing 1g of Vancomycin HCl must be diluted with at least 200ml of diluent. The desired dose, diluted in the manner, should be administered by intermittent intravenous infusion over a period of at least 60 minutes.
Compatibility with other Drugs and Intravenous Fluids: 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, Lactated Ringer's Injection, Lactated Ringers and 5% Dextrose Injection, Normosol-M and 5% Dextrose Isolyte E. Vancomycin HCl solution has a low pH and may cause physical instability of other compounds. **Parenteral drug products should be inspected visually for particulate matter and discolorations prior to administration whenever solution or container permits.**

INSTRUCTIONS:
Store below 30°C.
Protect from sunlight & moisture.
Keep out of the reach of children.

HOW SUPPLIED:
VANBACT I.V. injection is supplied as sterile, lyophilized powder in vials that contain either 500mg Vancomycin HCl or 1g Vancomycin HCl.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ دھوپ اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
NABIQASIM INDUSTRIES (PVT) LTD.
17/24, Korangi Industrial Area,
Karachi - Pakistan.
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