SUMMARY PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE MEDICINAL PRODUCT:

Vanbact I.V Injection 1gm

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Vanbact I.V Injection 500mg:

Each vial of lyophilized powder contains:

Vancomycin Hydrochloride USP equivalent to Vancomycin 500mg

Vanbact I.V Injection 1gm:

Each vial of lyophilized powder contains:

Vancomycin Hydrochloride USP equivalent to Vancomycin 1g

Excipients:

Vanbact I.V Injection 500mg:

Sterile water for injection..... 10ml

Vanbact I.V Injection 1gm:

Sterile water for injection..... 20ml
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Description:

Vanbact I.V Injection 500mg:

Injection, Light tan colored powder/cake.

Vanbact I.V Injection 1gm:

Injection, Light tan colored powder/cake.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

Vancomycin Hydrochloride 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

Hydrochloride is indicated for initial therapy when Methicillin Resistant Staphylococci are suspected but after susceptibility data are available, therapy should be adjusted accordingly. Vancomycin Hydrochloride 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.

4.2 Posology and method of 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 Hydrochloride, 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 Hydrochloride may be warranted in these patients.

The safety and efficacy of Vancomycin Hydrochloride 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 Hydrochloride 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 Hydrochloride 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 Hydrochloride 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 Hydrochloride 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.

4.3 Contraindications:

Known hypersensitivity to Vancomycin Hydrochloride.

4.4 Special warnings and precautions for use:

Warnings:

Rapid bolus administration (e.g. over several minutes) may be associated with exaggerated hypotension and rarely cardiac arrest. Vancomycin Hydrochloride 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 Hydrochloride 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 Hydrochloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Vancomycin Hydrochloride 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 Hydrochloride is administered to a nursing woman.

4.5 Interaction with other medicinal products and other forms of interaction:

Ototoxic and Nephrotoxic Drugs:

Concurrent or sequential use with other ototoxic and/or nephrotoxic drugs (e.g., aminoglycosides, amphotericin B, bacitracin, cisplatin, colistin, furosemide, polymyxin B) may result in additive toxicity and should be avoided, if possible. Monitor renal and auditory function intensely if used concomitantly with an ototoxic and/or nephrotoxic agent.

Aminoglycosides:

In vitro evidence of synergistic antibacterial activity against S. aureus, nonenterococcal group D streptococci (S. bovis), enterococci, and viridans streptococci.

Increased risk of ototoxicity and/or nephrotoxicity.

Used to therapeutic advantage, but consider possible increased risk of ototoxicity and/or nephrotoxicity.

Anesthetics:

Possible increased risk of anaphylactoid reactions and increased risk of vancomycin infusion reactions in patients receiving anesthetic agents; erythema and histamine-like flushing reported.

Risk of infusion-related adverse effects may be minimized if vancomycin is given by IV infusion (over ≥1 hour) prior to induction of anesthesia.

4.6. Fertility, Pregnancy and Lactation

Fertility:

Reproduction studies in rats and rabbits at doses up to 1 and 1.1 times the maximum recommended human dose (MRHD) based on body surface area, respectively, have revealed no teratogenic effects. No effects on foetal weight or development were seen with the same doses in rats or slightly lower doses in rabbits (0.74 times the MRHD). No other definitive fertility studies have been performed.

Pregnancy:

It is not known whether Vancomycin Hydrochloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Vancomycin Hydrochloride should be given to a pregnant woman only if clearly needed.

Lactation: 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 Hydrochloride is administered to a nursing woman.

4.7. Effects on ability to drive and use machines:

Not Applicable.

4.8. Undesirable effects:

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 Hydrochloride 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It

allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare

professionals are asked to report any suspected adverse reactions via Pharmacovigilance

Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

4.9. Overdose:

Amberlite resin XAD-4 has been reported to be of limited benefit. Haemofiltration effectively removes vancomycin from the blood.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties and Pharmacokinetic properties:

Pharmacodynamics:

Vancomycin is an amphoteric glycopeptide antimicrobial substance produced by the growth of certain strains of Nocardia orientalis. It is bactericidal against many gram-positive organisms.

Pharmacokinetics:

Vancomycin is poorly absorbed by mouth. It is given intravenously for the treatment of systemic infections.

The mean elimination half-life of vancomycin from plasma is 4 to 6 hours in subjects with normal renal function. In the first 24 hours, about 75% of an administered dose of vancomycin is excreted in the urine by glomerular filtration. Mean plasma clearance is about 0.06 L/kg/hour, and mean renal clearance is about 0.05 L/kg/hour. Renal dysfunction slows excretion of vancomycin. In anephric patients, the average half-life of elimination is 7.5 days. The distribution coefficient is from 0.3 to 0.69 L/kg. There is no apparent metabolism of the drug.

Vancomycin is not effectively removed by either haemodialysis or peritoneal dialysis; there have been no reports of vancomycin clearance with haemoperfusion.

Total systemic and renal clearance of vancomycin may be reduced in the elderly.

Protein binding is approximately 55% as measured by ultra filtration at vancomycin serum concentrations of 10 to 100 micrograms/L. Clinically effective concentrations of this antibiotic in the blood are usually achieved and maintained by its intravenous administration, moreover, inhibitory concentrations can be demonstrated in pleural, pericardial, ascitic and synovial fluids, in urine, in peritoneal dialysis fluid, and in atrial appendage tissue. Vancomycin does not readily diffuse across the meninges into the cerebrospinal fluid.

Measurable serum concentrations of vancomycin may occur in patients treated with oral vancomycin for active pseudomembranous colitis due to Clostridium difficile.

5.2 Preclinical safety data:

Although no long-term studies in animals have been performed to evaluate carcinogenic potential, no mutagenic potential of vancomycin was found in standard laboratory tests. Reproduction studies in rats and rabbits at doses up to 1 and 1.1 times the maximum recommended human dose (MRHD) based on body surface area, respectively, have revealed no teratogenic effects. No effects on foetal weight or development were seen with the same doses in rats or slightly lower doses in rabbits (0.74 times the MRHD). No other definitive fertility studies have been performed.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients

Vanbact I.V Injection 500mg:

Sterile water for injection..... 10ml

Vanbact I.V Injection 1gm:

Sterile water for injection..... 20ml

6.2 Incompatibilities:

None.

6.3 Shelf life:

Vanbact I.V Injection 500mg-36 months.

Vanbact I.V Injection 1gm-36 months.

6.4 Special precautions for storage:

Store below 30°C.

Protect from sunlight & moisture.

Keep out of the reach of children.

6.5 Nature and contents of container:

Each pack contains a glass vial containing 500mg or 1gm of Vancomycin Hydrochloride with 10ml or 20ml of sterile water for injection as diluent.

6.6 Special precautions for disposal and other handling

Refer “4.2 Posology and method of administration”.

7. MARKETING AUTHORISATION HOLDER:

Nabiqasim Industries (Pvt.) Ltd.

17/24, Korangi Industrial Area,

Korangi,

Karachi – Pakistan.

8. MARKETING AUTHORISATION NUMBER:

H2022/CTD7563/14729

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORISATION:

Vanbact I.V Injection 1gm-18th August, 2011.

10. DATE OF REVISION OF THE TEXT:

2026.

11. DOSIMETRY

Not applicable