Summary Product Characteristics (SmPC)

1. Name of the medicinal product
VANOGOOD

2. Qualitative and Quantitative composition
Each Combipack contains:
Vancomycin Hydrochloride for Injection USP
Each Vial Contains:
Vancomycin Hydrochloride USP
Eq. To Vancomycin.....500 mg
Sterile Water for Injection (USP).....10 ml
For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Dry Injection.
An off white powder filled in clear colourless glass vial properly sealed & properly labelled.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Vancomycin is indicated in all age groups for the treatment of the following infections (see sections 4.2, 4.4 and 5.1):
• 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
• bacteraemia that occurs in association with, or is suspected to be associated with any of the above.

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.

Oral administration

Vancomycin is indicated in all age groups for the treatment of Clostridium difficile infection (CDI) (see sections 4.2, 4.4 and 5.1).

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

For intravenous infusion only.
For preparation of solution for infusion, please refer to section **Special precautions for disposal and other handling**.
Concentrations of no more than 5 mg/mL are recommended. In selected patients in need of fluid restriction, a concentration up to 10 mg/mL may be used; use of such higher concentrations may increase the risk of infusion-related events. Infusions should be given over at least 60 minutes. In adults, if doses exceeding 500 mg are used, a rate of infusion of no more than 10 mg/min is recommended. Infusion related events may occur, however, at any rate or concentration.
The dose and duration of treatment should be adjusted individually and according to the underlying type and severity of infection, and patient factors such as age and renal function.
Vancomycin levels can be measured to aid dose adjustments.

Measurement of serum concentrations:

Following multiple intravenous doses, peak serum concentrations, measured two hours after infusion is complete, range from 18-26 mg/L. Trough levels measured immediately prior to the next dose should be 5-10 mg/L. Ototoxicity has been associated with serum drug levels of 80- 100mg/L, but this is rarely seen when serum levels are kept at or below 30 mg/L.

Patients with normal renal function:

Adults and children above 12 years of age:

The recommended daily intravenous dose is 2000 mg (2 g), given as 500 mg every 6 hours or 1000 mg (1 g) every 12 hours. Improvement is usually seen within 48 to 72 hours. The total duration of administration is determined by the type and severity of the infection and the clinical response of the patient.
For bacterial endocarditis, the generally accepted regimen is 1000 mg (1g) 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.
If Vancomycin is co-administrated with an aminoglycoside (e.g. gentamycin) patients should be monitored carefully for signs of neurotoxicity and ototoxicity.
The dosage should be adjusted when renal disturbance occurs (see section **Interaction with other medicinal products and other forms of interaction**).
Peri-operative prophylaxis against bacterial endocarditis: Adults receive 1000 mg (1g) vancomycin intravenously prior to surgery (prior to induction of anaesthesia) and depending on time and type of surgery, the dose of 1000 mg (1g) of vancomycin IV 12 hours postoperatively can be given.

Children one month to 12 years of age:

40 mg/kg/day: The dose must be divided and usually in to four doses (e.g. 10mg/kg every 6 hours). Each dose should be administered over at least 60 min.

Newborn infants (full-term):

0-7 days of age: A starting dose of 15 mg/kg, followed by 10 mg/kg every 12 hours. 7-30 days of age: A starting dose of 15 mg/kg, followed by 10 mg/kg every 8 hours. Each dose should be administered over at least 60 min.

Close monitoring of serum vancomycin concentrations may be warranted in these patients.

The elderly:

Dosage reduction may be necessary to a greater extent than expected because of decreasing renal function (see below). Monitor auditory function, see **Special warnings and precautions for use**.

Pregnancy:

It has been reported that significantly increased doses may be required to achieve therapeutic serum concentrations in pregnant patients.

Patients with impaired renal function:

In patients with impaired renal function, dosage regimen of vancomycin must be modified in response to degree of renal impairment, severity of infection, susceptibility of causative organism and serum concentrations of the drug. A suggested starting dose in patients with impaired renal function is 15 mg/kg with subsequent doses based mainly on renal function and serum concentrations of the drug.

Accumulation of the drug may occur with prolonged therapy and regular monitoring of serum levels should be carried out. The following guide is provided. This data is not valid for functionally anephric patients on dialysis.

Creatinine Clearance mL/min/kg	**Vancomycin Dose mg/kg/24 hrs**
2.0	30.9
1.5	23.2
1.0	15.4
0.5	7.7
0.2	3.1

In anephric patients, a loading dose of 15 mg/kg body weight should be given with subsequent dosage of 1.9 mg/kg/24hrs. Since individual maintenance doses of 250 mg – 1 g are convenient in patients with marked renal impairment, a dose may be given every several days rather than on a daily basis. In anuria a dose of 1g every 7-10 days has been recommended.

In patients on haemodialysis, the drug is not significantly removed by haemodialysis. A dose of 1g of vancomycin every seven days produces effective blood levels. Serum levels should be monitored to avoid drug accumulation and resultant toxicity. The serum half-life ranges from 120 to 216 hours.
In patients undergoing peritoneal dialysis, the half-life of vancomycin has been reported at around 18 hours. To prevent undue lowering of serum levels during peritoneal dialysis, an additional amount of vancomycin could be added to the dialysate in a concentration of 25 microgram per mL.

Patients with impaired liver function:

The availability of data in patients with impaired liver function is limited. Available data do not indicate the need for dose adjustment in mild or moderate liver function impairment.

Oral administration:

The contents of vials for parenteral administration may be used.
Adults and the elderly: The usual daily dose given is 500 mg in divided doses for 7 to 10 days, although up to 2 g/day have been used in severe cases. The total daily dosage should not exceed 2g. Each dose may be reconstituted in 30 mL water and either given to the patient to drink, or administered by nasogastric tube.
Children: The usual daily dose is 40 mg/kg in three or four divided doses for 7 to 10 days. The total daily dosage should not exceed 2g.
Common flavouring syrups may be added to the solution at the time of administration to improve the taste.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.
Vancomycin should not be administered intramuscularly due to the risk of necrosis at the site of administration.

4.4 Special warnings and precautions for use

Warnings:

Hypersensitivity reactions

Serious and occasionally fatal hypersensitivity reactions are possible (see sections 4.3 and 4.8). In case of hypersensitivity reactions, treatment with vancomycin must be discontinued immediately and the adequate emergency measures must be initiated.

In patients receiving vancomycin over a longer-term period or concurrently with other medications which may cause neutropenia or agranulocytosis, the leukocyte count should be monitored at regular intervals. All patients receiving vancomycin should have periodic haematologic studies, urine analysis, liver and renal function tests.

Vancomycin should be used with caution in patients with allergic reactions to teicoplanin, since cross hypersensitivity, including fatal anaphylactic shock,

may occur.

Spectrum of antibacterial activity

Vancomycin has a spectrum of antibacterial activity limited to Gram-positive organisms. It is not suitable for use as a single agent for the treatment of some types of infections unless the pathogen is already documented and known to be susceptible or there is a high suspicion that the most likely pathogen(s) would be suitable for treatment with vancomycin.

The rational use of vancomycin should take into account the bacterial spectrum of activity, the safety profile and the suitability of standard antibacterial therapy to treat the individual patient.

Ototoxicity

Ototoxicity, which may be transitory or permanent (see section 4.8) 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. Experience with other antibiotics suggests that deafness may be progressive despite cessation of treatment. To reduce the risk of ototoxicity, blood levels should be determined periodically and periodic testing of auditory function is recommended.

The elderly are particularly susceptible to auditory damage. Monitoring of vestibular and auditory function in the elderly should be carried out during and after treatment. Concurrent or sequential use of other ototoxic substances should be avoided.

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.

The frequency of infusion-related reactions (hypotension, flushing, erythema, urticaria and pruritus) increases with the concomitant administration of anaesthetic agents (see section 4.5). This may be reduced by administering vancomycin by infusion over at least 60 minutes, before anaesthetic induction.

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 (see section 4.8). Most of these reactions occurred within a few days and up to eight weeks after commencing treatment with vancomycin.

At the time of prescription patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, vancomycin should be withdrawn immediately and an alternative treatment considered. If the patient has developed a SCAR with the use of vancomycin, treatment with vancomycin must not be restarted at any time.

Administration site related reactions

Pain and thrombophlebitis may occur in many patients receiving intravenous vancomycin and are occasionally severe. The frequency and severity of thrombophlebitis can be minimized by administering the medicinal product slowly as a dilute solution (see section 4.2) and by changing the sites of infusion regularly.

The efficacy and safety of vancomycin has not been established for the intrathecal, intralumbar and intraventricular routes of administration.

Parental administration

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.

Regular monitoring of the blood levels of vancomycin is indicated in high dose therapy and longer-term use, particularly in patients with renal dysfunction or impaired faculty of hearing as well as in concurrent administration of nephrotoxic or ototoxic substances, respectively (see sections 4.2 and 4.5)

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.

Oral administration

Intravenous administration of vancomycin is not effective for the treatment of Clostridium difficile infection. Vancomycin should be administered orally for this indication.

Testing for Clostridium difficile colonization or toxin is not recommended in children younger than 1 year due to high rate of asymptomatic colonisation unless severe diarrhoea is present in infants with risk factors for stasis such as Hirschsprung disease, operated anal atresia or other severe motility disorders. Alternative aetiologies should always be sought and Clostridium difficile enterocolitis be proven.

Potential for Systemic Absorption

Absorption may be enhanced in patients with inflammatory disorders of the intestinal mucosa or with Clostridium difficile-induced pseudomembranous colitis. These patients may be at risk for the development of adverse reactions, especially if there is a concomitant renal impairment. The greater the renal impairment, the greater the risk of developing the adverse reactions associated with the parenteral administration of vancomycin. Monitoring of serum vancomycin concentrations of patients with inflammatory disorders of the intestinal mucosa should be performed.

Nephrotoxicity

Serial monitoring of renal function should be performed when treating patients with underlying renal dysfunction or patients receiving concomitant therapy with an aminoglycoside or other nephrotoxic drugs.

Ototoxicity

Serial tests of auditory function may be helpful in order to minimise the risk of ototoxicity in patients with an underlying hearing loss, or who are receiving concomitant therapy with an ototoxic agent such as an aminoglycoside.

Drug interactions with anti-motility agents and proton pump inhibitors

Anti-motility agents should be avoided and proton pump inhibitor use should be reconsidered.

Development of Drug-Resistant Bacteria

Oral vancomycin use increases the chance of vancomycin-resistant Enterococci populations in the gastrointestinal tract. As a consequence, prudent use of oral vancomycin is advised

Cardiovascular and cerebrovascular effects

Cases of Kounis syndrome have been reported in patients treated with vancomycin. Kounis syndrome has been defined as cardiovascular symptoms secondary to an allergic or hypersensitive reaction associated with constriction of coronary arteries and potentially leading to myocardial infarction.

4.5 Interaction with other medicinal products and other forms of interaction

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

Infusion-related events may be minimised by the administration of vancomycin as a 60-minute infusion prior to anaesthetic induction.

Other potentially nephtoroxic or ototoxic medicinal products: Concurrent or sequential systemic or topical use of other potentially neurotoxic or nephrotoxic drugs, such as gentamycin, amphotericin B, streptomycin, neomycin, kanamycin, amikacin, tobramycin, bacitracin, polymixin B, colistin, viomycin or cisplatin, may potentiate the nephrotoxicity and/or ototoxicity of vancomycin and consequently requires careful monitoring. See **Posology and method of administration** with regard to dosage adjustment in case of use with an aminoglycoside.

Muscle relaxants: There is an increased potential of neuromuscular blockade with concomitant administration of vancomycin and neuromuscular blocking agents.

4.6 Pregnancy and lactation

Pregnancy:

No sufficient safety experience is available regarding vancomycin during human pregnancy.

Reproduction toxicological studies on animals do not suggest any effects on the development of the embryo, foetus or gestation period (see section **Preclinical safety data**).

However, vancomycin penetrates the placenta and a potential risk of embryonal and neonatal ototoxicity and nephrotoxicity cannot be excluded. Therefore vancomycin should be given in pregnancy only if clearly needed and after a careful risk/benefit evaluation.

Lactation:
Vancomycin is excreted in human milk. Caution should be excercised when given to breastfeeding mothers because of potential adverse reactions in the infant (disturbances in the intestinal flora with diarrhoea, colonisation with yeast like fungi and possibly sensibilisation).
Considering the importance of this medicine for nursing mother, the decision to stop breastfeeding should be considered.

4.7 Effects on ability to drive and use machines
Vancomycin has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects
The most common adverse reactions are phlebitis and pseudo-allergic reactions in connection with too rapid intravenous infusion of vancomycin.
Infusion related events:
During or shortly after rapid infusion anaphylactoid reactions may occur, including hypotension, dyspnea, urticaria or pruritus. Redness of the skin on the upper body (Red man syndrome), pain and cramps in chest or back muscle can occur.
The reactions abate when administration is stopped, generally between 20 minutes and 2 hours. Vancomycin should be infused slowly (for more than 60 minutes - see section **Special warnings and precautions for use**).
Otoxicity has primarily been reported in patients given high doses, or concomitant treatment with other ototoxic medicinal product, or had a pre-existing reduction in kidney function or hearing.
Blood and the lymphatic system disorder:
Rare: Thrombocytopenia, neutropenia, agranulocytosis, eosinophilia.
Immune system disorders:
Rare: Anaphylactic reactions, hypersensitivity reactions.
Ear and labyrinth disorders:
Uncommon: Transient or permanent loss of hearing.
Rare: Tinnitus, dizziness.
Cardiac disorders:
Very rare: Cardiac arrest.
Vascular disorders:
Common: Decrease in blood pressure, thrombophlebitis. Very rare: Vasculitis
Respiratory, thoracic and mediastinal disorders:
Common: Dyspnoea, stridor.

Gastrointestinal disorders: Rare:
Nausea, diarrhoea
Very rare: Pseudomembranous enterocolitis.
Skin and subcutaneous tissue disorders:
Common: Exanthema and mucosal inflammation, pruritus, urticaria.
Very rare: Exfoliative dermatitis, Stevens-Johnson syndrome, linear IgA bullous dermatosis, Lyell's syndrome.
Renal and urinary disorders:
Common: Renal insufficiency manifested primarily by increased serum creatinine. Rare: Interstitial nephritis, acute renal failure.
General disorders and administration site conditions:
Common: Phlebitis, redness of the upper body and the face, pain and spasm of the chest and back muscles.
Rare: Drug fever, shivering.
Drug rash with eosinophilia and systemic symptoms (DRESS syndrome) has been reported during post-marketing experience.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important as it allows continued monitoring of the benefit–risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions to the marketing authorisation holder or, where applicable, via the national reporting system

4.9 Overdose
Toxicity due to overdose has been reported. 500 mg IV to a child, 2 year of age, resulted in lethal intoxication. Administration of a total of 56 g during 10 days to an adult resulted in renal insufficiency. In certain high-risk conditions (e. g. in case of severe renal impairment) high serum levels and oto- and nephrotoxic effects can occur.
Measures in case of overdose
- A specific antidote is not known.
- Symptomatic treatment while maintaining renal function is required.
- Vancomycin is poorly removed from the blood by haemodialysis or peritoneal dialysis. Haemofiltration or haemoperfusion with polysulfone resins have been used to reduce serum.

5. Pharmacological properties
5.1 Pharmacodynamic properties
Pharmacological classification: Other Antibacterials

Pharmacotherapeutic group: Glycopeptide
Antibacterials
ATC code: J01XA01
Mode 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 bactericidal for dividing microorganisms.

PK/PD relationship: Vancomycin activity is considered to be time-dependent - that is, antimicrobial activity depends on the duration that the drug level exceeds the minimum inhibitory concentration (MIC) of the target organism.

Mechanism of resistance: Acquired resistance to glycopeptides is based on acquisition of various van gene complexes and alteration of the Dalanyl- D-alanine target to D-alanyl-D-lactate or D- alanyl-D-serine which bind vancomycin poorly, because a critical site for hydrogen bonding is missing. This form of resistance is especially seen in Enterococcus faecium.
The reduced susceptibility or resistance to vancomycin in Staphylococcus is not well understood. Several genetic elements and multiple mutations are required. Cross-resistance with teicoplanin has been reported.

Susceptibility:
Vancomycin is active against gram-positive bacteria. Gram-negative bacteria are resistant. The MIC breakpoints separating susceptible from resistant organisms are as follows:

	Susceptible	**Resistant**
Staphylococcus species	≤2 mg/L	>2 mg/L
Enterococcus species	≤4 mg/L	>4 mg/L
Streptococcus species	≤2 mg/L	>2 mg/L
Streptococcus pneumoniae	≤2 mg/L	>2 mg/L
Gram-positive anaerobes	≤2 mg/L	≤2 mg/L
Non species related*	≤2 mg/L	>4 mg/L

* Non-species related breakpoints have been determined mainly on the basis of PK/PD data and are independent of MIC distributions of specific species. They are for use only for species that have not been given a species-specific breakpoint and not for those species where susceptibility testing is not recommended.

The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly

when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infections is questionable.

Commonly susceptible species Gram positive

Enterococcus faecalis.
Staphylococcus aureus
Staphylococcus coagulase negative Streptococcus species Streptococcus pneumoniae Clostridium species

Species for which acquired resistance may be a problem

Enterococcus faecium

Inherently resistant Gram negative bacteria
Chlamydia species
Mycobacteria
Mycoplasma species
Rickettsia species

5.2 Pharmacokinetic properties

Vancomycin appears in various body fluids, including pleural, pericardial, synovial and ascetic fluids.

A single intravenous dose of 1g in adults produces plasma concentrations of 15 to 30µg/mL 1 hour after 1- to 2-hour infusion.

Vancomycin is metabolized only to a low extent. After parenteral administration it is excreted almost completely as microbiologically active substance (approx. 75-90% within 24 hours) through glomerular filtration via the kidneys. Biliary excretion is insignificant (less than 5% of a dose).

The serum elimination half-life is about 4-6 hours in adults with normal renal-function and 2, 2-3 hours in children. In patients with impaired renal function the serum elimination half-life can be significantly increased (up to 7.5 days).

The total systematic and renal clearance of vancomycin may be reduced in the elderly due to the natural decrease in glomerular filtration.

The volume of distribution is 0.4 – 1L/kg. The binding of vancomycin to protein has been reported in the literature to range from 10% to 50%. Factors that affect the overall activity of vancomycin include its tissue distribution, inoculum size, and protein-binding effects.

Vancomycin is not significantly absorbed from the normal gastro-intestinal tract and is therefore not effective by the oral route for infections other than staphylococcal enterocolitis and pseudomembranous colitis due to *Clostridium difficile*.

Orally administered vancomycin does not usually enter the systemic circulation even when inflammatory lesions are present. Measurable serum concentrations may occur infrequently in patients with active *C. difficile* – induced pseudomembranous colitis and, in the presence of renal impairment, the possibility of accumulation exists.
Administration of vancomycin oral solution, 2 g daily for 16 days to anephric patients with no inflammatory bowel disease, gave serum levels of <0.66 g/mL. With doses of 2 g daily, concentration of 3100 mg/kg can be found in the faeces and levels of <1 g/mL can be found in serum of patients with normal renal function who have pseudomembranous colitis.

5.3 Preclinical safety data
Non-clinical data reveal no special hazard for humans based on conventional studies of safety
pharmacology and repeated dose toxicity. Limited data on mutagenic effects show negative results, long-term studies in animals regarding a carcinogenic potential are not available.
In teratogenicity studies, where rats and rabbits received doses approximately corresponding to the human dose based on body surface (mg/m^2), no direct or indirect teratogenic effects were observed. Animal studies of the use during the perinatal/postnatal period and regarding effects on fertility are not available.

6. Pharmaceutical particulars
6.1 List of excipients
Sterile water for Injection USP

6.2 Incompatibilities
Vancomycin solutions have a low pH that may cause chemical or physical instability if mixed with other compounds. Mixing with alkaline solutions should be avoided. Therefore, each parental solution should be checked visually for precipitation and discolouration prior to use.

This medicinal product must not be mixed with other solutions for infusion except those mentioned in section 6.6.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store below 30°C. Protect from light moisture.

6.5 Nature and contents of container
500 mg clear Glass Vial with 10ml Water for Injection.

6.6 Special precautions for disposal and other handling

Reconstituted solutions containing 50 mg/ml of vancomycin should be further diluted depending on the method of administration.
Preparation of the reconstituted solution
Dissolve the powder in 10 ml of sterile Water for injection
One ml of reconstituted solution contains 50 mg of vancomycin.
Appearance of reconstituted solution
After reconstitution the solution is clear and colorless to slightly yellowish brown without visible particles.
For storage conditions of the reconstituted medicinal product, see section 6.3.
Preparation of final diluted Solution for infusion
Reconstituted solutions containing 50 mg/ml of vancomycin should be further diluted.
Suitable diluents are:
• 5% Glucose Injection
• 0.9% Sodium Chloride Injection
• 5% Glucose Injection with 0.9% Sodium Chloride Injection
• Ringer's Lactate Injection

Intermittent infusion:

Reconstituted solution containing 500 mg vancomycin (50 mg/ml) must be diluted further with at least 100 ml diluent (to 5 mg/ml)

The concentration of vancomycin in Solution for infusion should not exceed 5 mg/ml.

The desired dose should be administered slowly by intravenous use at a rate of no more than 10 mg/minute, for at least 60 minutes or even longer.

Continuous infusion:

This should be used only if treatment with an intermittent infusion is not possible. Dilute 1000 mg to 2000 mg of dissolved vancomycin in a sufficient amount of the above suitable diluent and administer it in the form of a drip infusion, so that the patient will receive the prescribed daily dose in 24 hours.

Oral Administration

The contents of vials for parenteral administration may be used.

The reconstituted solutions containing 500 mg and 1000 mg of vancomycin can be diluted in 30 ml of water and given to the patient or administered through a nasogastric tube.

Appearance of diluted solution

After dilution the solution is clear and colorless without visible particles.

For storage conditions of the diluted medicinal product, see section 6.3.

Before administration, the reconstituted and diluted solutions should be inspected visually for particulate matter and discoloration. Only clear, and colorless solution free from particles should be used.

Disposal

Vials are for single use only. Unused medicinal products must be discarded.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
PROMED PHARMACEUTICALS LTD
P.O BOX 22953-00100
NAIROBI, KENYA

Manufacturer:
OM BIOMEDIC PVT. LTD.
Plot No. 7 & 8,
National Highway No. 8,
Vasai Phata, Vasai (East), Thane 401208
Maharashtra State, INDIA

8. Marketing Authorisation Number(s)
H2025/CTD12040/26278

9. Date of first Authorisation/ Renewal of the Authorisation
2025 November 03

10. DATE OF REVISION OF THE TEXT
03/2021