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Physician's Package Insert עלון לרופא

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# VANCO TEVA®

# ונקו טבע®

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INJECTION להזרקה לתוך הוריד

## Composition

Each vial of lyophilizate contains:

*Active Ingredient*

| | |
|---|---|
| Vancomycin (as hydrochloride) | 500 mg or 1 g |

*Other ingredients*

Sodium hydroxide, hydrochloric acid (for pH adjustment)

## Action

Vancomycin hydrochloride, a tricyclic glycopeptide antibiotic, is obtained from *Nocardia orientalis* (formerly *Streptomyces orientalis*).

Vancomycin hydrochloride is bactericidal, and appears to act by binding to the bacterial cell wall with resultant blockage of glycopeptide polymerization. This mode of action differs from that of the penicillins, which produce instant inhibition of cell wall synthesis and secondary damage to the cytoplasmic membrane. Also, there is evidence that vancomycin hydrochloride selectively inhibits RNA synthesis and changes the permeability of the bacterial cell membrane.

Vancomycin hydrochloride is active against many gram-positive bacteria such as staphylococci, including *Staphylococcus aureus* and *Staphylococcus epidermidis* (including heterogenous methicillin- resistant strains); streptococci, including *Streptococcus pyogenes*, *Streptococcus pneumonia*, (including penicillin-resistant strains), *Streptococcus agalactiae*, the viridans group, *Streptococcus bovis;* enterococci (e.g. *Enterococcus fecalis* [formerly *Streptococcus fecalis*]); *Clostridium difficile* (including toxigenic strains implicated in *Pseudomembranous enterocolitis)*; and diphtheroids. Other organisms that are susceptible to vancomycin hydrochloride *in vitro* include *Listeria monocytogenes,* Lactobacillus species, Actinomyces species, Clostridium species, and Bacillus species.

Vancomycin hydrochloride is not active *in vitro* against gram-negative bacteria, fungi or mycobacteria. Cross-resistance between vancomycin hydrochloride and other antibiotics has not been demonstrated.

Vancomycin hydrochloride is administered intravenously for treatment of systemic infections. Intramuscular injection is painful, since the drug is very irritating to tissue; therefore, vancomycin hydrochloride must not be administered by the intramuscular route.

### *Pharmacokinetics*

Vancomycin hydrochloride is poorly absorbed after oral dosing. Studies have shown that in subjects with normal renal function, multiple intravenous administration of 1 g vancomycin (15 mg/kg), infused over 60 minutes, produces mean plasma levels of about 63 µg/ml immediately after the infusion, about 23 µg/ml 2 hours post infusion, and about 8 µg/ml 11 hours after the completion of the infusion. Multiple intravenous administration of 500 mg administered over 30 minutes results in mean plasma levels of approximately 49 µg/ml after the infusion, about 19 µg/ml 2 hours post-infusion, and about 10 µg/ml 6 hours following completion of the infusion. The plasma levels obtained during multiple administration are comparable to those obtained after administration of a single dose.

Vancomycin hydrochloride is about 55% bound to serum proteins. Following intravenous dosing of vancomycin hydrochloride, inhibitory concentrations are found in pericardial, pleural, synovial and ascitic fluids, in peritoneal dialysis fluid, in urine, and in atrial appendage tissue. Vancomycin hydrochloride does not diffuse readily across normal meninges. It penetrates into the spinal fluid when the meninges are inflamed. Small amounts of vancomycin hydrochloride are excreted into the bile.

The serum elimination half-life of vancomycin in adults with normal kidney function reportedly averages 4-6 hours; accumulation tending to occur at 6- or 12- hour intervals after 2-3 days of intravenous administration. Serum elimination half-life is increased in patients with impaired renal function. In a study, the elimination half-life reportedly averaged 146.7 hours in patients with a creatinine clearance of less than 10 ml/minute, and 32.3 hours in patients with a creatinine clearance of 10-60 ml/minute.

Vancomycin hydrochloride, administered parenterally, is eliminated principally by glomerular filtration. During the first 24 hours, about 75% of the dose of vancomycin hydrochloride administered is eliminated via the urine. However, only small amounts of vancomycin hydrochloride are eliminated in the bile after intravenous dosing.

Apparently metabolism of the drug does not occur. Despite the fact that vancomycin hydrochloride is not removed effectively by either peritoneal or hemodialysis, there have been reports of increased vancomycin hydrochloride clearance with hemoperfusion and hemofiltration. In the elderly total systemic and renal clearance of vancomycin hydrochloride may be reduced. (See Warnings).

## Indications

Vancomycin hydrochloride is indicated for the treatment of severe or serious infections due to susceptible strains of methicillin- resistant (β-lactam-resistant) staphylococci. It is also indicated for administration to penicillin-allergic patients, as well as patients who have failed to respond to, or who cannot receive other drugs, including cephalosporins or penicillins, and for infections due to vancomycin-susceptible organisms that are resistant to other antimicrobial drugs.

Vancomycin hydrochloride is indicated for first-line therapy when methicillin-resistant staphylococci are suspected, but when susceptibility data become available, appropriate therapy should be instituted.

Vancomycin hydrochloride is effective in the treatment of staphylococcal endocarditis as well as in other infections due to staphylococci, including lower respiratory tract infections, septicemia, skin and skin- structure infections and bone infections. Antibiotic therapy is indicated as an adjunct to appropriate surgical measures when staphylococcal infections are purulent and localized.

For endocarditis due to *Streptococcus viridans* or *Streptococcus bovis*, vancomycin hydrochloride has been shown to be effective alone or in combination with an aminoglycoside. Vancomycin hydrochloride has been shown to be effective only in combination with an aminoglycoside for endocarditis due to enterococci (eg, *Enterococcus fecalis)*.

Vancomycin hydrochloride has been shown to be effective for the treatment of diphtheroid endocarditis. In early-onset prosthetic valve endocarditis caused by *Staphylococcus epidermidis* or diptheroids, vancomycin hydrochloride has been administered successfully in combination with either rifampin, an aminoglycoside or combined with both drugs.

Bacteriologic cultures of specimens should be obtained for isolation and identification of causative organisms and determination of susceptibilities to vancomycin hydrochloride.

*Oral Therapy*

Vancomycin hydrochloride injection may be given orally for the treatment of antibiotic-associated Pseudomembranous colitis due to *Staphylococcus enterocolitis* and *Clostridium difficile*. Vancomycin hydrochloride is not effective orally when administered for other types of infection.

## Contraindications

Known hypersensitivity to vancomycin hydrochloride.

## Warnings

Exaggerated hypotension including shock and, rarely cardiac arrest, may occur with rapid bolus administration (e.g., over several minutes).

Administration of vancomycin hydrochloride injection in a dilute solution should take place over a period of not less than 60 minutes to avoid rapid-infusion-related reactions. Cessation of the infusion generally results in quick reversal of these reactions.

Ototoxicity, which may be transient or permanent, has been documented in patients receiving vancomycin hydrochloride. It has been reported mainly in patients who have been administered excessive doses and who are receiving concomitant therapy with another ototoxic agent, such as an aminoglycoside, or who have an underlying loss of hearing.

Vancomycin hydrochloride should be administered cautiously in patients with kidney dysfunction because the risk of toxicity is substantially increased by high, prolonged blood concentrations. For patients with renal impairment the dosage of vancomycin hydrochloride must therefore be adjusted.(see Precautions, Dosage and Administration).

Some patients with inflammatory disorders of the intestinal mucosa may have significant systemic absorption of oral vancomycin and, therefore, may be at risk for the development of adverse reactions associated with the parenteral administration of vancomycin. The risk is greater in patients with renal impairment. It should be noted that the total systemic and renal clearances of vancomycin are reduced in the elderly.

Vancomycin should also be avoided in patients with previous hearing loss. If it is used in such patients, the dose should be regulated, if possible, by periodic determination of the drug level in the blood. Deafness may be preceded by tinnitus.

The elderly are more susceptible to auditory damage. Experience with other antibiotics suggests that deafness may be progressive despite cessation of treatment. Vancomycin should be administered with caution in patients allergic to teicoplanin, since allergic cross reactions between vancomycin and teicoplanin have been reported.

Patients with borderline renal function and individuals over the age of 60 should be given serial tests of auditory function and of vancomycin blood levels. All patients receiving the drug should have periodic haematological studies, urine analysis and renal function tests.

**Vancomycin is very irritating to tissue, and causes injection site necrosis when injected intramuscularly; it must be administered intravenously. Injection site pain and thrombophlebitis occur in many patients receiving vancomycin and are occasionally severe.** The frequency and severity of thrombophlebitis can be minimised by administering the drug slowly as a dilute solution (2.5 to 5.0 g/l) and by rotating the sites of infusion (see also Precautions).

Reports have revealed that administration of vancomycin by the intraperitoneal route during continuous ambulatory peritoneal dialysis (CAPD) has resulted in a syndrome of chemical peritonitis.To date, this syndrome has ranged from cloudy dialysate alone to a cloudy dialysate accompanied by variable degrees of abdominal pain and fever.This syndrome appears to be short-lived after discontinuation of intraperitoneal vancomycin.

Prescribing vancomycin in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

*Teratogenicity*

Data are insufficient to yield information regarding the effect of vancomycin.

Teratology studies have been performed at 5 times the human dose in rats and 3 times the human dose in rabbits, and have revealed no evidence of harm to the foetus due to vancomycin. In a controlled clinical study, the potential ototoxic and nephrotoxic effects of vancomycin hydrochloride on infants were evaluated when the drug was administered to pregnant women for serious staphylococcal infections complicating intravenous drug abuse. Vancomycin hydrochloride was found in cord blood. No sensorineural hearing loss or nephrotoxicity attributable to vancomycin was noted. One infant, whose mother received vancomycin in the third trimester, experienced conductive hearing loss that was not attributable to vancomycin. hydrochloride on the fetus.

*Effect on Fertility and Reproduction*

It is not known whether vancomycin hydrochloride can affect reproduction capacity since animal reproduction studies have not been performed with vancomycin hydrochloride.

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*Use in Pregnancy*

Safety of use in pregnancy has not been established

Because vancomycin was administered only in the second and third trimesters, it is not known whether it causes fetal harm. Vancomycin should be given in pregnancy only if clearly needed and blood levels should be monitored carefully to minimize the risk of fetal toxicity. It has been reported, however, that pregnant patients may require significantly increased doses of vancomycin to achieve therapeutic serum concentrations

*Use in Breastfeeding*

Vancomycin hydrochloride is eliminated in human milk. Due to the potential for adverse reactions, it should be decided whether to discontinue the drug or to discontinue nursing, considering the significance of the therapy to the mother.

*Use in Pediatrics*

In premature neonates and young infants, it may be appropriate to confirm desired vancomycin hydrochloride serum concentrations. Concomitant administration of vancomycin hydrochloride and anesthetic agents has been associated with erythema and histamine-like flushing in children (see Drug Interactions).

*Use in Elderly Patients*

Vancomycin hydrochloride dosage schedules should be adjusted in elderly patients, since the normal decline of glomerular filtration with aging may result in increased vancomycin hydrochloride plasma concentrations if dosage is not adjusted.

*Use in Patients with Renal Insufficiency*

Due to its potential ototoxicity and nephrotoxicity, vancomycin should be used with care in patients with renal insufficiency and the dose should be reduced according to the degree of renal impairment. The risk of toxicity is appreciably increased by high blood concentrations or prolonged therapy. Blood levels should be monitored and renal function tests should be performed regularly.

## Adverse Reactions

*Infusion-Related Events*

Anaphylactoid reactions may occur either during or soon after rapid infusion of vancomycin hydrochloride, including urticaria, pruritus, wheezing, dyspnea, or hypotension. Rapid infusion may also precipitate flushing of the upper body and redness of the neck, muscle spasm and pain in the back and chest. Such adverse events generally cease within 20 minutes but may continue for several hours.

In animal studies, bradycardia and hypotension occurred when vancomycin hydrochloride was administered in large doses and at high concentrations and rates. Such adverse events occur infrequently if vancomycin hydrochloride is administered over 60 minutes by a slow infusion.

Rapid bolus injection may give hypotension, bradycardia, cardiogenic shock and rarely cardiac arrest.

*Nephrotoxicity*

Rare cases of renal failure, primarily manifested by elevated serum creatinine or BUN levels, specially in patients administered large doses of vancomycin hydrochloride, has been documented. Rare reports of interstitial nephritis have been documented. Most of these cases have developed in patients who had preexisting renal impairment or who were receiving aminoglycosides concomitantly. Following cessation of vancomycin hydrochloride therapy, azotemia resolved in most patients.

*Ototoxicity*

Loss of hearing associated with vancomycin hydrochloride therapy has been documented. Most of these patients had a preexisting hearing loss, renal impairment or were receiving concomitant treatment with an ototoxic drug. Rare cases of dizziness, tinnitus and vertigo have been reported.

Tinnitus, possibly preceding onset of deafness, may occur and should be regarded as an indication to discontinue treatment.

*Hematopoietic Effects*

Reversible neutropenia has been reported starting 1 week or more after initiation of treatment with vancomycin hydrochloride, or following a total dose of more than 25 g. Neutropenia appears to resolve rapidly on cessation of vancomycin hydrochloride therapy. Thrombocytopenia has been noted rarely.

Reversible agranulocytosis has been noted rarely although a causal relationship has not been established. Eosinophilia has been reported.

*Phlebitis*

Inflammation at the injection site has been noted.

*Gastrointestinal*

Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment (see Warnings).

*Miscellaneous*

Infrequently, therapy with vancomycin hydrochloride has been associated with nausea, rashes (including exfoliative dermatitis), eosinophilia, chills, drug fever, hypersensitivity reactions, anaphylaxis, Stevens-Johnson's syndrome, toxic epidermal necrolysis and rare cases of vasculitis. Linear IgA bullous dermatosis has also been reported. If a bullous disorder is suspected, the drug should be discontinued and specialist dermatological assessment should be carried out.

Chemical peritonitis has been reported following intraperitoneal administration of vancomycin (see Warnings).

***Post Marketing Reports***

The following adverse reactions have been identified during post-approval use of vancomycin. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to the drug exposure:

Skin and Subcutaneous Tissue Disorders

Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)

## Precautions

Clinically significant plasma levels have been observed in some patients who have been administered multiple doses of vancomycin hydrochloride orally for active *Clostridium difficile*-induced *Pseudomembranous colitis*.

Prolonged administration of vancomycin hydrochloride may give rise to overgrowth of nonsusceptible organisms. It is essential that the patient be monitored carefully. If superinfection occurs while under treatment with vancomycin hydrochloride, proper action should be instituted. *Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents including vancomycin and may range in severity from mild diarrhea to fatal colitis.

Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C.difficil*e.
*C.difficile* produces toxins A and B which contribute to the development of CDAD.
Hypertoxin producing strains of *C.difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use . Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C.difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C.difficil*e, and surgical evaluation should be instituted as clinically indicated.

Regular monitoring of kidney function should be carried out and special care should be exercised in following appropriate dosing schedules; thereby reducing the risk of nephrotoxicity when treating patients with underlying kidney impairment or patients receiving concomitant therapy with an aminoglycoside (see Dosage and Administration).

Serial monitoring of auditory function may be of assistance so that the risk of ototoxicity can be diminished.

Reversible neutropenia has been noted in patients receiving vancomycin hydrochloride therapy (see Adverse Reactions). Patients who are scheduled to undergo extended treatment with vancomycin hydrochloride, or those who are receiving concomitant drugs that may induce neutropenia, should undergo regular monitoring of the leukocyte count.

Vancomycin hydrochloride must be administered by a secure intravenous route of administration since it is irritating to tissue. Tenderness, necrosis and pain occur with inadvertent extravasation or with intramuscular injection of vancomycin hydrochloride. Thrombophlebitis may develop, the frequency and severity of which can be diminished by giving the drug slowly as a dilute solution (2.5-5 g/liter) and by rotating the sites of infusion.

It has been reported that the prevalence of infusion-related reactions (including flushing, hypotension, urticaria, pruritus and erythema) increases with the concomitant administration of anesthetic agents. Infusion-related reactions may be decreased by the administration of vancomycin hydrochloride as a 60-minute infusion prior to anesthetic induction.

The efficacy and safety of vancomycin hydrochloride administration intrathecally (intralumbar or intraventricular routes) have not been evaluated.

***Drug Interactions***

***Vancomycin/Anesthetic Agents***: Concomitant administration of anesthetic agents and vancomycin hydrochloride has been linked with erythema and histamine- like flushing (see Warnings- Use in Pediatrics) and anaphylactoid reactions.

There have been reports that the frequency of infusion-related events increases with the concomitant administration of anesthetic agents. Infusion-related events may be minimised by the administration of vancomycin as a 60-minute infusion prior to anesthetic induction.

***Vancomycin/Neurotoxic/Nephrotoxic Drugs***: Sequential and/or concurrent topical or systemic use of other potentially neurotoxic and/or nephrotoxic drugs, such as amphotericin B, aminoglycosides, polymyxin B, viomycin, bacitracin, colistin or cisplatin, necessitates cautious monitoring.

## Information for Patients

Patients should be counseled that antibacterial drugs including vancomycin, should only be used to treat bacterial infections.They do not treat viral infections (e.g., the common cold). When vancomycin is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by vancomycin or other antibacterial drugs in the future.

Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

## Dosage and Administration

*Prior to administration, parenteral drug products should be inspected visually for particulate matter and discoloration, whenever solution and container permit.*

*For intravenous administration and oral use only and not for intramuscular administration (see also Warnings).*

Infusion-related reactions are linked to both the rate of administration and the concentration of vancomycin hydrochloride. Rates of no more than 10 mg/min and concentrations of no more than 5 mg/ml are advised in adults.

In selected patients requiring fluid restriction, a concentration up to 10 mg/ml may be administered; administration of such higher concentrations may increase the risk of infusion-related reactions. Infusions should be given over at least 60 minutes. Infusion-related reactions may occur, however, at any concentration or rate.

*Intravenous Therapy*

The efficacy and safety of vancomycin hydrochloride administered intrathecally (intralumbar or intraventricular routes) have not been evaluated. Intermittent infusion is the advised method of administration.

*Patients with Normal Renal Function*

*Adults*

The normal daily intravenous dosage is 2 g divided either as 1 g every 12 hours or 500 mg every 6 hours. Each dose should be given at no more than 10 mg/min, or over a period of at least 60 minutes, whichever is longer. Further patient considerations, such as age or obesity, may require adjustment of the normal intravenous daily dose.

*Elderly*

Dosage reduction may be necessary to a greater extent than expected because of decreasing renal function. Auditory function should be monitored.

*Children*

The normal intravenous dosage of vancomycin hydrochloride is 10 mg/kg body weight per dose administered every 6 hours (total daily dosage 40 mg/kg body weight). Each dose should be given over a period of at least 60 minutes.

*Infants and Neonates*

In young infants and neonates, the total daily intravenous dosage may be less. In both infants and neonates, an initial dose of 15 mg/kg body weight is advised, followed by 10 mg/kg body weight every 12 hours for neonates in the first week of life and every 8 hours thereafter up to the age of 1 month. Each dose should be given over 60 minutes. Close surveillance of plasma levels of vancomycin hydrochloride may be required in these patients.

*Patients with Impaired Renal Function and Elderly Patients*

*Note*: Regular monitoring of serum levels is advised in such patients, as accumulation has been reported, especially after prolonged therapy.

Dosage must be adjusted appropriately for patients with kidney dysfunction. In premature infants and the elderly, dosage reductions greater than expected may be required because of reduced kidney function. Measurement of vancomycin hydrochloride plasma levels can be of assistance in optimizing therapy, specially in seriously ill patients with unstable kidney function. Vancomycin hydrochloride plasma levels can be measured by use of high-pressure liquid chromatography, fluorescence polarization immunoassay, radioimmunoassay, fluorescence immunoassay, or microbiologic assay.

If creatinine clearance can be determined or estimated accurately, the dosage for the majority of patients with impaired renal function can be determined by consulting the following table. The dosage of vancomycin hydrochloride per day, expressed in mg is about 15 times the glomerular filtration rate in ml/min:

Dosage Table for Vancomycin
in Patients with Kidney Dysfunction

| Creatinine Clearance | Vancomycin Hydrocloride |
|---|---|
| ml/min | 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 starting dose should be not less than 15 mg/kg body weight, even in patients with mild to moderate kidney impairment.

*Measurement of serum concentrations*: Following multiple intravenous doses, peak serum concentrations, measured 2 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 80-100 mg/L, but this is rarely seen when serum levels are kept at or below 30 mg/L.

*Oral Therapy*

Orally administered vancomycin hydrochloride is indicated for the treatment of staphylococcal enterocolitis or antibiotic- associated *Pseudomembranous colitis* due to *Clostridium difficile*.

The normal adult oral dosage of vancomycin hydrochloride is 0.5 - 2 g daily given in 3 or 4 divided doses for 7-10 days. In children, the usual oral dosage of vancomycin is 40 mg/kg body weight daily given in 3 or 4 divided doses for 7 to 10 days. The total daily dosage of oral vancomycin hydrochloride should not exceed 2 g.

The dose may be diluted in 30 ml of water and given to the patient to drink. In order to improve the taste for oral administration common flavoring syrups may be added.

The diluted solution may be administered via a nasogastric tube.

## Preparation of the Solution

*Reconstitution*

***Vanco Teva 500 mg***

Reconstitution is made by adding 10 ml Water for Injection to the lyophilizate.

***Vanco Teva 1g***

Reconstitution is made by adding 20 ml Water for Injection to the lyophilizate.

In both cases, the concentration of the resulting solution is 50 mg/ml.

The lyophilizate dissolves completely, resulting in a clear light brown solution.

*Further Dilution*

Further dilution is required before administration.

The reconstituted solution, containing 500 mg or 1 g of vancomycin, must be diluted with at least 100 ml or 200 ml of diluent, respectively. The prescribed appropriate dose should be administered by intermittent intravenous infusion over a period of 60 minutes (see Dosage and Administration).

*Compatibility with Intravenous Fluids*

Vancomycin solutions may be diluted with the following intravenous fluids:

- 5% Dextrose Injection
- 0.9% Sodium Chloride Injection

***Storage recommendations***

***Reconstituted solution:***

Chemical and physical in- use stability has been demonstrated for 24 hours at 25°C and 96 hours at 2- 8°C.

***Further diluted solution:***

Solutions for infusion that are diluted to 5 mg/ml with 5% Glucose Injection or 0.9% Sodium Chloride Injection are chemically and physically stable in a refrigerator (2°C - 8°C) for 96 hours, or at 25°C for 24 hours.

From a microbiological point of view the medicinal product should be used immediately unless reconstitution and dilution has taken place in controlled and validated aseptic conditions.

If not used immediately, in- use storage times and conditions are the responsibility of the user.

Vancomycin solutions have a low pH and may cause chemical or physical instability when they are mixed with other compounds.

## Overdosage

General supportive measures are recommended, with preservation of glomerular filtration; removal of vancomycin hydrochloride by dialysis is poor. Hemoperfusion and hemofiltration with polysulfone resin have been documented to result in increased vancomycin hydrochloride clearance.

## Storage

Store the unreconstituted vial below 25°C. Protect from light.

## Presentation

Vials of lyophilizate containing 500 mg or 1 g Vancomycin (as Hydrochloride).

## Product Registration No.:

Vanco Teva 500 mg: 133 63 27437 00
Vanco Teva 1 g: 133 62 29157 00

## Manufacturer

Teva Pharmaceutical Works Private Limited Company,
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## Licence Holder

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