DESCRIPTION: Vancomycin Hydrochloride for Injection, USP is a lyophilized powder, for preparing intravenous (IV) infusions, in vials containing the equivalent of 5 g or 10 g vancomycin base. 500 mcg of the base are equivalent to 0.34 mmol. When reconstituted with Sterile Water for Injection to a concentration of 50 mg/mL for the 5 g vial and 100 mg/mL for the 10 g vial, the pH of the solution is between 2.5 and 4.5. Vancomycin Hydrochloride for Injection, USP should be administered intravenously in diluted solution (see DOSAGE AND ADMINISTRATION).

Vancomycin is a triocyclic glycopeptide antibiotic derived from Amycolatopsis orientalis (formerly Nocardia orientalis). Vancomycin hydrochloride has the following structural formula:

![Vancomycin Structural Formula](http://example.com/vancomycin_formula.png)

A pharmacy bulk package is a sterile dosage form containing many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for IV infusion.

FURTHER DILUTION IS REQUIRED BEFORE USE.

CLINICAL PHARMACOLOGY:

Vancomycin is poorly absorbed after oral administration.

In subjects with normal kidney function, multiple IV dosing of 1 g of vancomycin (15 mg/kg) infused over 60 minutes produces mean plasma concentrations of approximately 63 mcg/mL immediately at the completion of infusion, mean plasma concentration of approximately 23 mcg/mL two hours after infusion, and mean plasma concentrations of approximately 8 mcg/mL 11 hours after the end of the infusion.

Multiple dosing of 500 mg infused over 30 minutes produces mean plasma concentrations of about 49 mcg/mL at the completion of infusion, mean plasma concentrations of about 19 mcg/mL two hours after infusion, and mean plasma concentrations of about 10 mcg/mL six hours after infusion. The plasma concentrations during multiple dosing are similar to those after a single dose.

The mean elimination half-life of vancomycin from plasma is four to six hours in subjects with normal renal function. In the first 24 hours, about 75% of an administered dose of vancomycin is excreted in urine by glomerular filtration. Mean plasma clearance is about 0.058 L/kg/hr, and mean renal clearance is about 0.048 L/kg/hr. 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 0.45 L/kg. There is no apparent metabolism of the drug. About 60% of an intraperitoneal dose of vancomycin administered during peritoneal dialysis is absorbed systemically in six hours. Serum concentrations of about 10 mcg/mL are achieved by intraperitoneal injection of 30 mg/kg of vancomycin. Vancomycin is not effectively removed by either hemodialysis or peritoneal dialysis; there have been no reports of vancomycin clearance with hemoperfusion.

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

Vancomycin is approximately 55% serum protein bound as measured by ultrafiltration at vancomycin serum concentrations of 10 to 100 mcg/mL. After IV administration of vancomycin, inhibitory concentrations are present in pleural, pericardial, ascitic and synovial fluids; in urine; in peritoneal dialysis fluid; and in atrial appendage tissue. Vancomycin does not readily diffuse across normal meninges into the spinal fluid; but, when the meninges are inflamed, penetration into the spinal fluid occurs.

Microbiology:

The bactericidal action of vancomycin results primarily from inhibition of cell-wall biosynthesis. In addition, vancomycin alters bacterial-cell membrane permeability and RNA synthesis. There is no cross-resistance between vancomycin and other antibiotics. Vancomycin is not active in vitro against gram-negative bacilli, mycobacteria, or fungi.

Synergy:

The combination of vancomycin and an aminoglycoside acts synergistically in vitro against many strains of Staphylococcus aureus, Streptococcus bovis, enterococci, and the viridans group streptococci.

Vancomycin has been shown to be active against most strains of the following microorganisms, but not when added to other antibiotics as described in INDICATIONS AND USAGE:

**Aerobic gram-positive microorganisms**

Diphtheroids

Enterococci (e.g., Enterococcus faecalis)

Staphylococci, including Staphylococcus aureus and Staphylococcus epidermidis (including heterogeneous methicillin-resistant strains)

Streptococcus bovis

Viridans group streptococci

The following in vitro data are available, but their clinical significance is unknown.

Vancomycin exhibits in vitro MICs of 1 mcg/mL or less against most (≥90%) strains of streptococci listed below and MICs of 4 mcg/mL or less against most (≥90%) strains of other listed microorganisms; however, the safety and effectiveness of vancomycin in treating clinical infections due to these microorganisms have not been established in adequate and well-controlled clinical trials.

**Aerobic gram-positive microorganisms**

Listeria monocytogenes

Streptococcus pyogenes

Streptococcus pneumoniae (including penicillin-resistant strains)

Streptococcus agalactiae

**Anaerobic gram-positive microorganisms**

Actinomyces species

Lactobacillus species

**Susceptibility Tests**

**Dilution Techniques**

Quantitative methods are used to determine antimicrobial minimum inhibitory concentrations (MICs). These MICs provide estimates of the susceptibility of bacteria to antimicrobial compounds. The MICs should be determined using a standardized procedure. Standardized procedures are based on a dilution method (broth or agar) or equivalent with standardized inoculum concentrations and standardized concentrations of vancomycin. The MIC values should be interpreted according to the following criteria:

For testing aerobic microorganisms otherwise than streptococci:

<table>
<thead>
<tr>
<th>MIC (mcg/mL)</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤4</td>
<td>Susceptible (S)</td>
</tr>
<tr>
<td>8 to 16</td>
<td>Intermediate (I)</td>
</tr>
<tr>
<td>≥32</td>
<td>Resistant (R)</td>
</tr>
</tbody>
</table>

* A 8-lactamase test using an inoculum ≥ 10⁵ CFU/mL (or direct colony growth) and a nitrocefin-based substrate should be performed to detect either ampicillin or penicillin resistance among enterococci due to 8-lactamase production.

For testing streptococci other than Streptococcus pneumoniae:

<table>
<thead>
<tr>
<th>MIC (mcg/mL)</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤4</td>
<td>Susceptible (S)</td>
</tr>
<tr>
<td>≥4 but &lt;16</td>
<td>Intermediate (I)</td>
</tr>
<tr>
<td>≥16</td>
<td>Resistant (R)</td>
</tr>
</tbody>
</table>

* Interpretive criteria applicable only to tests performed by broth microdilution method using cation-adjusted Mueller-Hinton broth with 0.5% lysed horse blood.

The current absence of data on resistant strains precludes defining any categories other than “Susceptible”.

Strains yielding MIC results suggestive of a “non-susceptible” category should be submitted to a reference laboratory for further testing. A report of “Susceptible” indicates that the pathogen is likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable. A report of “Intermediate” indicates that the result should be considered equivocal, and if the microorganism is not fully susceptible to one or more feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage

PHARMA BULK PACKAGE—Not for Direct Infusion

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Vancomycin Hydrochloride for Injection, USP and other antibacterial drugs, Vancomycin Hydrochloride for Injection, USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.
of drug can be used. This category also provides a buffer zone which prevents small uncontrolled technical factors from causing major discrepancies in interpretation. A report of “Resistant” indicates that the pathogen is not likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achieved in plasma. Standardized susceptibility test procedures must be used. Standardized susceptibility test procedures require the use of laboratory control microorganisms to control the technical aspects of the laboratory procedures. Standard vancomycin powder should provide the following MIC values:

**Microorganism**  
MIC (mg/mL)  
**Enterococcus faecalis**  
ATCC 29212  
1.0 to 4  
**Staphylococcus aureus**  
ATCC 29213  
0.5 to 2  
**Streptococcus pneumoniae**  
ATCC 49619  
0.12 to 0.5

† Interpretative criteria applicable only to tests performed by broth microdilution method using cation-adjusted Mueller-Hinton broth with 2 to 5% lyzed horse blood.

### Diffusion Techniques

Quantitative methods that require measurement of zone diameters also provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds. One such standardized procedure requires the use of Mueller-Hinton agar plates containing 30-mcg vancomycin to test the susceptibility of microorganisms to vancomycin.

Reports from the laboratory providing results of the standard single-disk susceptibility test with a 30-mcg vancomycin disk should be interpreted according to the following criteria:

- **Zone Diameter (mm)**  
  **Interpretation**  
  **Resistant (R)**  
  ≥15 ( Susceptible (S))  
  13 to 15  
  Intermediate (I)  
  ≤13  
  Susceptible (S)  

- **For testing enterococci**:  
- **Zone Diameter (mm)**  
  **Interpretation**  
  **Resistant (R)**  
  ≥17  
  15 to 16  
  Intermediate (I)  
  ≤14  
  Susceptible (S)

- **For testing other streptococci**:  
- **Zone Diameter (mm)**  
  **Interpretation**  
  **Resistant (R)**  
  ≥17 ( Susceptible (S))  
  15 to 16  
  Intermediate (I)  
  ≤13  
  Susceptible (S)

### Interpretive Criteria

† Interpretative criteria applicable only to tests performed by disk diffusion method using Mueller-Hinton agar plates containing 30-mcg vancomycin.

- **A direct nitrocefin-β-lactamase test using direct colony growth should be performed to detect either spontaneous emergence among enterococci due to β-lactamase production.**
- **When testing for enterococci resistance to vancomycin, the disks must be loaded with 1 µg of vancomycin and examined using transmitted light. The presence of a haze or any growth within the zone of inhibition indicates resistance.** Those enterococci with intermediate zones of inhibition should be tested by a standardized procedure based on a dilution method (broth or agar) or equivalent.

### Dosage and Administration

**Zone Diameter (mm)**  
**Interpretation**  
**Resistant (R)**  
≥15 ( Susceptible (S))  
13 to 15  
Intermediate (I)  
≤13  
Susceptible (S)

- **A direct nitrocefin-β-lactamase test using direct colony growth should be performed to detect either spontaneous emergence among enterococci due to β-lactamase production.**
- **When testing for enterococci resistance to vancomycin, the disks must be loaded with 1 µg of vancomycin and examined using transmitted light. The presence of a haze or any growth within the zone of inhibition indicates resistance.** Those enterococci with intermediate zones of inhibition should be tested by a standardized procedure based on a dilution method (broth or agar) or equivalent.

### Antimicrobial Activity

**Microorganism**  
**Zone Diameter (mm)**  
**Staphylococcus aureus**  
ATCC 29213  
27 to 20  
**Streptococcus pneumoniae**  
ATCC 49619  
17 to 21

**Interpretative criteria applicable only to tests performed by broth microdilution method using cation-adjusted Mueller-Hinton broth with 5% defibrinated sheep blood and incubated in 5% CO2.

### Indications and Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Vancomycin Hydrochloride for Injection, USP and other antibacterial drugs, vancomycin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. In the absence of culture and susceptibility information, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

**Vancomycin Hydrochloride for Injection**  
USP is indicated for the treatment of serious or severe infections caused by susceptible strains of the following:  
- **Staphylococcus aureus** (including penicillin-resistant strains)  
- **Staphylococcus epidermidis**  
- **Streptococcus pneumoniae**  
- **Enterococcus faecalis** (e.g., E. faecalis), vancomycin has been reported to be effective only in combination with an aminglycocode for endocarditis caused by S. viridans or S. bovis. For endocarditis caused by enterococci (e.g., E. faecalis), vancomycin has been reported to be effective only in combination with an aminglycocode.

Vancomycin has been reported to be effective for the treatment of streptococcal endocarditis. Vancomycin has been used successfully in combination with either rifampin, an aminglycocode, or other antibiotics for the treatment of prosthetic valve endocarditis caused by S. epidermidis or diphtheroids.

### Contraindications

Vancomycin is contraindicated in patients with a history of hypersensitivity to this antibiotic.

### Warnings

- **Rapid bolus administration (e.g., over several minutes) may be associated with exaggerated hypotension and cardiac arrest.**
- **Vancomycin should be administered in a diluted solution over a period of at least 60 minutes to avoid infusion-related reactions.** Stopping the infusion usually results in a prompt cessation of these reactions.

### Dosage

Dosage of vancomycin must be adjusted for patients with impaired renal function (see PRECAUTIONS AND DOSAGE AND ADMINISTRATION).

### Precautions

**C. difficile** produce toxins A and B which contribute to the development of CDAD. Hyper-toxin production by C. difficile causes increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and/or vancomycin. 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.

### Adverse Reactions

Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

### Contraindications

Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotics are discontinued. Sometimes, diarrhea symptoms may not develop until two or more months after having taken the last dose of the antibiotic. If this occurs, patients should consult their physicians as soon as possible.

### Precautions

Patients should be counseled that antibiotic drugs including vancomycin should only be used to treat bacterial infections. Infection caused by organisms that are not susceptible to vancomycin may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, and treatment of the underlying condition is appropriate.

### Dosage and Administration

**C. difficile** produce toxins A and B which contribute to the development of CDAD. Hyper-toxin production by C. difficile causes increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and/or vancomycin. 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 may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, and treatment of the underlying condition is appropriate.
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.

Drug Interactions
Concomitant administration of vancomycin and anesthetic agents has been associated with histamine-like flushing (see Pediatric Use) and anaphylactoid reactions (see ADVERSE REACTIONS). Aminoglycosides can impair the renal or topical use of other potentially, neurotoxic and/or ototoxic drugs, such as amphotericin B, aminoglycosides, bacitracin, polymyxins B, colistin, viomycin, or cisplatin, when indicated requires careful monitoring.

Carcinogenesis, Mutagenesis, Impairment of Fertility
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. No definitive fertility studies have been performed.

Pregnancy
Teratogenic Effects: Pregnancy Category C
In a chorioallantoic membrane and myometrium administered to pregnant women for serious staphyloccocal infections that were complicated- on the use of vancomycin in the labor and delivery. Neonates in the first week of life and every 7 to 10 days has been recommended.

Infants and Neonates
In premature neonates and young infants, it may be appropriate to confirm desired vancomycin serum concentrations. Continuous administration of vancomycin and any other agents has been associated with erythema and histamine-like flushing in pediatric patients (see ADVERSE REACTIONS).

Geriatrics
The natural decrement of glomerular filtration with increasing age may lead to elevated vancomycin serum concentrations if dosing is not adjusted. The vancomycin dosage schedules should be adjusted in elderly patients (see DOSAGE AND ADMINISTRATION).

ADVERSE REACTIONS: Infections Related Events
During or soon after rapid infusion of vancomycin, patients may develop anaphylactoid reactions, including hypotension (see ANIMAL PHARMACOLOGY), wheezing, dyspnea, urticaria, or 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 is given by a slow infusion over 60 minutes. In studies of normal volunteers, infusion-related events did not occur when vancomycin was administered at a rate of 10 mg/min or less.

Nephrotoxicity
Renal failure, principally manifested by increases in creatinine or BUN concentrations, especially in patients administered large doses of vancomycin, has been reported rarely. Cases of interstitial nephritis have also been reported rarely. Most of these have occurred in patients who were given aminoglycosides concomitantly, who had preexisting kidney dysfunction. When vancomycin was discontinued, azotemia resolved in most patients.

Gastrointestinal
Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment (see WARNINGS). Ototoxicity
A few dozen cases of hearing loss associated with vancomycin therapy have been reported. Most of these patients had kidney dysfunction or a pre-existing hearing loss or were receiving concomitaneous treatment with other ototoxic drugs. Vertigo, dizziness, and tinnitus have been reported rarely.

Hematopoietic
Reversible neutropenia, usually starting 1 week or more after onset of therapy with vancomycin or after a total dosage of more than 25 g, has been reported in some patients. Neutropenia appears to be promptly reversible when vancomycin is discontinued. Thrombocyto-penia has not been reported. Although a causal relationship has not been established, reversible agranulocytosis (granulocytes <1000/mm3) has been reported rarely.

Phlebitis
Inflammation at the injection site has been reported.

Miscellaneous
Infrequently, patients have been reported to have had anaphylaxis, drug fever, nausea, chills, eosinophilia, rashes including exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis and vasculitis in association with administration of vancomycin. (Chemical peritonitis has been reported following intraperitoneal administration of vancomycin (see PRECAUTIONS).

Post Marketing Reports
The following serious 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 drug exposure.

Skin and Subcutaneous Tissue Disorders
Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)
OVERDOSAGE:
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. The median lethal intravenous dose is 319 mg/kg in rats and 400 mg/kg in mice.

To obtain up-to-date information about the treatment of overdose, a good resource is your certified Regional Poison Control Center. Telephone numbers of certified poison control centers are listed in the Physicians’ Desk Reference (PDR). In managing overdose, consider the possibility of multiple drug overdoses, interaction among drugs and unusual drug kinetics in your patient.

DOSAGE AND ADMINISTRATION:
Infusion-related events are related to both the concentration and rate of administration of vancomycin. Concentrations of no more than 5 mg/mL and rates of no more than 10 mg/min are recommended in adults (see also age-specific recommendations). 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. Infusion-related events may occur, however, at any concentration.

Patients with Normal Renal Function
Adults
The usual daily dose is 2 g divided either as 500 mg every 6 hours or 1 g every 12 hours. Each dose should be administered at no more than 10 mg/min, or over a period of at least 60 minutes. Other patients, since, such as in obese patients or those with liver disease, edema, or ascites; and (3) accompanied by debilitation, malnutrition, and inactivity.

The safety and efficacy of vancomycin administration by the intrathecal (intralumbar or intra-ventricular) route have not been assessed. Intermittent infusion is the recommended method of administration.

Compatibility with Other Drugs and IV Fluids
The following solutions are physically and chemically compatible (with 10 g vancomycin hydrochloride):

- 5% Dextrose Injection, USP
- 0.9% Sodium Chloride Injection, USP
- Lactated Ringer’s Injection, USP
- Normosol-M and 5% Dextrose 0.9% Sodium Chloride Injection, USP

Patients with Impaired Renal Function and Elderly Patients
Dosage adjustment must be made in patients with impaired renal function. In premature infants and the elderly, greater dosage reductions than expected may be necessary because of decreased renal function. Measurement of vancomycin serum concentrations can be helpful in optimizing therapy, especially in critically ill patients with changing renal function. Vancomycin serum concentrations can be determined by use of microbiologic and radioimmunoassay, fluorescence polarization immunoassay, fluoroimmunoassay or high-pressure liquid chromatography.

If creatinine clearance can be measured or estimated accurately (with CrCl <10 mL/min), the glomerular filtration rate in mL/min (see following table). The dosage of vancomycin per day in mg is about 15 mg/kg, even in patients with moderate renal insufficiency.

The initial dose should be no less than 15 mg/kg, even in infants exceeding moderate renal insufficiency. The table is not valid for functionally anephric patients. For such patients, an initial dose of 15 mg/kg of body weight should be given to achieve prompt therapeutic serum concentrations. The dose required to maintain stable concentrations is 1.9 mg/kg/24 hr. In patients with marked renal impairment, it may be more convenient to give maintenance doses of 250 to 1000 mg once every several days rather than administering the drug on a daily basis. In anuria, a dose of 1000 mg every 7 to 10 days has been recommended.

When only serum creatinine is known, the following formula (based on sex, weight and age of the patient) may be used to calculate creatinine clearance. Calculated creatinine clearances (mL/min) are only estimates. The creatinine clearance should be measured promptly.

<table>
<thead>
<tr>
<th>Men: Weight (kg)</th>
<th>Women: 0.85 x above value</th>
</tr>
</thead>
<tbody>
<tr>
<td>72 kg serum creatinine concentration (mg/dL)</td>
<td>3.0 mg/dL</td>
</tr>
</tbody>
</table>

The serum creatinine must represent a steady state of renal function or the estimated value for creatinine clearance will not be valid. Such a calculated clearance is an overestimate of actual clearance in patients with conditions: (1) characterized by decreased renal perfusion, such as shock, severe heart failure or oliguria; or (2) in which a normal relationship between muscle mass and total body water is not present, such as in obese patients or those with liver disease, edema, or ascites; and (3) accompanied by debilitation, malnutrition, and inactivity.

The safety and efficacy of vancomycin administration by the intrathecal (intralumbar or intraventricular) route have not been assessed. Intermittent infusion is the recommended method of administration.
Good professional practice suggests that compounded admixtures should be administered as soon after preparation as is feasible.

Vancomycin solution has a low pH and may cause physical instability of other compounds.

**DIRECTIONS FOR PROPER USE OF PHARMACY BULK PACKAGE:**

Pharmacy bulk packages are for use in a pharmacy admixture service only in a suitable work area, such as a laminar flow hood. They should be hung by the integral hanger or inserted into the ring sling (plastic hanging device) provided and suspended as a unit in the laminar flow hood. The container closure should be penetrated only one time utilizing a suitable sterile dispensing set which allows measured distribution of the contents. Use of a syringe and needle is not recommended as it may cause leakage. Swab bottle stopper with an antiseptic solution. Insert the dispensing set into the bottle using aseptic technique. (See graphic illustration below.)

**Instructions to use ring sling**

Once the sterile dispensing set has been inserted into the container, withdrawal of the contents should be accomplished without delay. However, if this is not possible, a maximum time of 4 hours from the initial entry may be allowed to complete fluid aliquoting/transfering operations. This time limit should begin with the introduction of solvent into the Pharmacy Bulk Package bottle. Discard the container no later than 4 hours after initial closure puncture.

**Preparation and Stability**

**5 g Bottle**

At the time of use, reconstitute by adding 100 mL of Sterile Water for Injection, USP to the 5 g bottle of dry, sterile vancomycin powder. The resultant solution will contain vancomycin equivalent to 500 mg/10 mL. **FURTHER DILUTION IS REQUIRED.**

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.

**10 g Bottle**

At the time of use, reconstitute by adding 95 mL of Sterile Water for Injection, USP to the 10 g bottle of dry, sterile vancomycin powder. The resultant solution will contain vancomycin equivalent to 500 mg/5 mL (1 g/10 mL). **FURTHER DILUTION IS REQUIRED.**

Reconstituted solutions of vancomycin (500 mg/5 mL) must be further diluted in at least 100 mL of a suitable infusion solution. For doses of 1 gram (10 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.

Parenteral drug products should be visually inspected for particulate matter and discol-oration prior to administration, whenever solution and container permit.

**For Oral Administration**

Oral vancomycin is used in treating antibiotic-associated pseudomembranous colitis caused by *C. difficile* and for staphylococcal enterocolitis. Vancomycin is not effective by the oral route for other types of infections. The usual adult total daily dosage is 500 mg to 2 g given in 3 or 4 divided doses for 7 to 10 days. The total daily dose in children is 40 mg/kg of body weight in 3 or 4 divided doses for 7 to 10 days. The total daily dosage should not exceed 2 g. The appropriate dose may be diluted in 1 oz of water and given to the patient to drink. Common flavoring syrups may be added to the solution to improve the taste for oral administration. The diluted solution may be administered via a nasogastric tube.