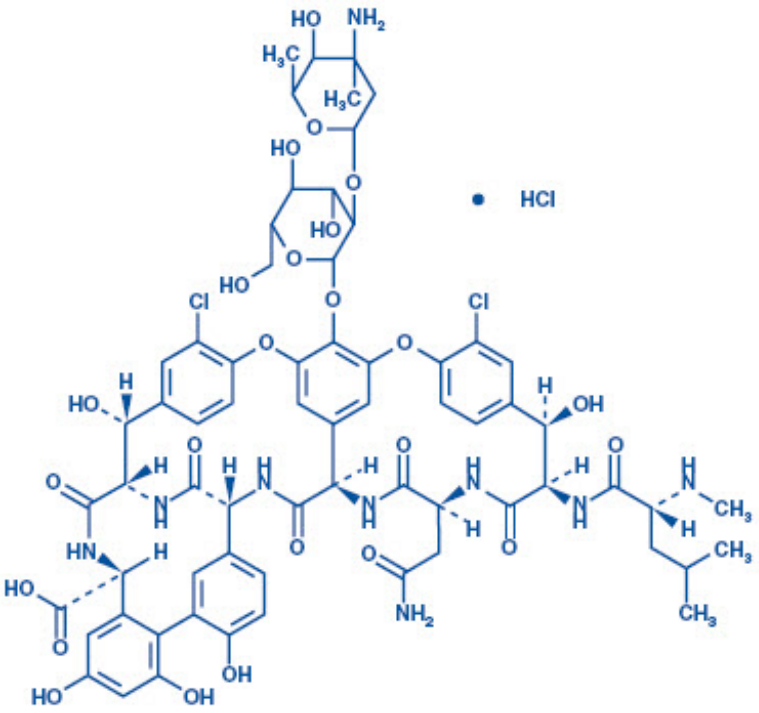
VANCOMYCIN HYDROCHLORIDE- vancomycin hydrochloride injection, solution
Baxter Healthcare Corporation

Vancomycin Injection, USP
For Intravenous Use Only

To reduce the development of drug-resistant bacteria and maintain the effectiveness of vancomycin and other antibacterial drugs, vancomycin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

DESCRIPTION

Vancomycin Injection, USP in the GALAXY plastic container contains vancomycin, added as Vancomycin Hydrochloride, USP. It is a tricyclic glycopeptide antibiotic drug derived from *Amycolatopsis orientalis* (formerly *Nocardia orientalis*). The molecular formula is $C_{66}H_{75}Cl_2N_9O_{24}$• HCl and the molecular weight is 1,485.71. Vancomycin hydrochloride has the following structural formula:



Vancomycin Injection, USP in the GALAXY plastic container is a frozen, iso-osmotic, sterile, nonpyrogenic premixed single-dose formulation. The composition of Vancomycin Injection, USP is available in the following strengths (See **HOW SUPPLIED/STORAGE AND HANDLING**):

- 500 mg/100 mL (5 mg/mL): containing 500 mg of vancomycin (equivalent to 513 mg of vancomycin hydrochloride); approximately 5 g of dextrose hydrous or 0.9 g of sodium chloride (equivalent to 354 mg total sodium content).
- 750 mg/150 mL (5 mg/mL): containing 750 mg of vancomycin (equivalent to 769 mg of vancomycin hydrochloride); approximately 7.5 g of dextrose hydrous or

1.35 g of sodium chloride (equivalent to 531 mg total sodium content).
- 1 g/200 mL (5 mg/mL): containing 1 g of vancomycin (equivalent to 1.025 g of vancomycin hydrochloride); approximately 10 g of dextrose hydrous or 1.8 g of sodium chloride (equivalent to 708 mg total sodium content).
- 1.25 g/250 mL (5 mg/mL): containing 1.25 g of vancomycin (equivalent to 1.281 g of vancomycin hydrochloride); approximately 12.5 g of dextrose hydrous.
- 1.5 g/300 mL (5 mg/mL): containing 1.5 g of vancomycin (equivalent to 1.538 g of vancomycin hydrochloride); approximately 15 g of dextrose hydrous.

The pH of the solution may have been adjusted with hydrochloric acid and/or sodium hydroxide. Thawed solutions have a pH in the range of 3.0 to 5.0. After thawing to room temperature, this solution is intended for intravenous use only.

This GALAXY container is fabricated from a specially designed multilayer plastic. Solutions are in contact with the polyethylene layer of this container and can leach out certain chemical components of the plastic in very small amounts within the expiration period. The suitability of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

In subjects with normal kidney function, multiple intravenous dosing of 1 g of vancomycin (15 mg/kg) infused over 60 minutes produces mean plasma concentrations of approximately 63 mcg/mL immediately after the completion of infusion, mean plasma concentrations of approximately 23 mcg/mL 2 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 2 hours after infusion, and mean plasma concentrations of about 10 mcg/mL 6 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 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 urine by glomerular filtration. Mean plasma clearance is about 0.058 L/kg/h, and mean renal clearance is about 0.048 L/kg/h. 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 0.43 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 6 hours. Serum concentrations of about 10 mcg/mL are achieved by intraperitoneal injection of 30 mg/kg of vancomycin. However, the safety and efficacy of the intraperitoneal use of vancomycin has not been established in adequate and well-controlled trials (see PRECAUTIONS).

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, both *in vitro* and in clinical infections as described in the INDICATIONS AND USAGE section.

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* MIC's of 1 mcg/mL or less against most (≥90%) strains of streptococci listed below and MIC's 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 Test Methods

For specific information regarding susceptibility test interpretive criteria and associated test methods and quality control standards recognized by FDA for this drug, please see: http://www.fda.gov/STIC.

INDICATIONS AND USAGE

Vancomycin is indicated for the treatment of serious or severe infections caused by susceptible strains of methicillin-resistant (beta-lactam-resistant) staphylococci. It is indicated for penicillin-allergic patients, for 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 is indicated for initial therapy when methicillin-resistant staphylococci are suspected, but after susceptibility data are available, therapy should be adjusted accordingly.

Vancomycin is effective in the treatment of staphylococcal endocarditis. Its effectiveness has been documented in other infections due to staphylococci, including septicemia, bone infections, lower respiratory tract infections, skin and skin structure infections. When staphylococcal infections are localized and purulent, antibiotics are used as adjuncts to appropriate surgical measures.

Vancomycin has been reported to be effective alone or in combination with an aminoglycoside for endocarditis caused by *Streptococcus 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 aminoglycoside.

Vancomycin has been reported to be effective for the treatment of diphtheroid endocarditis. Vancomycin has been used successfully in combination with either rifampin, an aminoglycoside, or both in early-onset prosthetic valve endocarditis caused by *S. epidermidis* or diphtheroids.

Specimens for bacteriologic cultures should be obtained in order to isolate and identify causative organisms and to determine their susceptibilities to vancomycin.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of vancomycin 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. When culture and susceptibility information are available, 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.

CONTRAINDICATION

Vancomycin is contraindicated in patients with known hypersensitivity to this antibiotic. Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

WARNINGS

Infusion Reactions

Rapid bolus administration (*e.g.*, over several minutes) may be associated with exaggerated hypotension, including shock, and, rarely, cardiac arrest.

Vancomycin should be administered over a period of not less than 60 minutes to avoid rapid-infusion-related reactions. Stopping the infusion usually results in prompt cessation of these reactions.

Nephrotoxicity

Systemic vancomycin exposure may result in acute kidney injury (AKI). The risk of AKI increases as systemic exposure/serum levels increase. Monitor renal function in all patients receiving vancomycin, especially patients with underlying renal impairment, patients with co-morbidities that predispose to renal impairment and patients receiving concomitant therapy with a drug known to be nephrotoxic.

Ototoxicity

Ototoxicity has occurred in patients receiving vancomycin. It may be transient or permanent. It has been reported mostly in patients who have been given excessive doses, who have an underlying hearing loss, or who are receiving concomitant therapy with another ototoxic agent, such as an aminoglycoside. Vancomycin should be used with caution in patients with renal insufficiency because the risk of toxicity is appreciably increased by high, prolonged blood concentrations.

Severe Dermatologic Reactions

Severe dermatologic reactions such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP), and linear IgA bullous dermatosis (LABD) have been reported in association with the use of vancomycin. Cutaneous signs or symptoms reported include skin rashes, mucosal lesions, and blisters.

Discontinue Vancomycin Injection at the first appearance of signs and symptoms of TEN, SJS, DRESS, AGEP, or LABD.

Dosage of vancomycin must be adjusted for patients with renal dysfunction (see **PRECAUTIONS** and **DOSAGE AND ADMINISTRATION**).

Clostridioides Difficile Associated Diarrhea (CDAD)

Clostridioides difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Vancomycin Injection, USP, 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. difficile*.

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. difficile*, and surgical evaluation should be instituted as clinically indicated.

Hemorrhagic Occlusive Retinal Vasculitis (HORV)

Hemorrhagic occlusive retinal vasculitis, including permanent loss of vision, occurred in patients receiving intracameral or intravitreal administration of vancomycin during or after cataract surgery. The safety and efficacy of vancomycin administered by the intracameral or the intravitreal route have not been established by adequate and well-controlled trials. Vancomycin is not indicated for prophylaxis of endophthalmitis.

PRECAUTIONS

Prolonged use of vancomycin may result in the overgrowth of nonsusceptible microorganisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken. In rare instances, there have been reports of pseudomembranous colitis due to *C. difficile* developing in patients who received intravenous vancomycin.

Risk of High Sodium Load:

Each 100mL solution of Vancomycin Injection, USP contains 0.9 g of Sodium Chloride, USP. Avoid use of Vancomycin Injection, USP with Sodium Chloride, USP in patients with congestive heart failure, elderly patients and patients requiring restricted sodium intake.

Serial tests of auditory function may be helpful in order to minimize the risk of ototoxicity.

Reversible neutropenia has been reported in patients receiving vancomycin (see ADVERSE REACTIONS). Patients who will undergo prolonged therapy with vancomycin or those who are receiving concomitant drugs that may cause neutropenia should have periodic monitoring of the leukocyte count.

Vancomycin is irritating to tissue and must be given by a secure intravenous route of administration. Pain, tenderness, and necrosis occur with inadvertent extravasation. Thrombophlebitis may occur, the frequency and severity of which can be minimized by slow infusion of the drug and by rotation of venous access sites.

There have been reports that the frequency of infusion-related events (including hypotension, flushing, erythema, urticaria, and pruritus) increases with the concomitant administration of anesthetic agents. Infusion-related events may be minimized by the administration of vancomycin as a 60-minute infusion prior to anesthetic induction. The safety and efficacy of vancomycin administered by the intrathecal (intralumbar or intraventricular) route or by the intraperitoneal route have not been established by adequate and well-controlled trials.

Reports have revealed that administration of sterile 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 a 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.

Drug Interactions

Concomitant administration of vancomycin and anesthetic agents has been associated with erythema and histamine-like flushing (see Usage in Pediatrics under PRECAUTIONS) and anaphylactoid reactions (see ADVERSE REACTIONS).

Monitor renal function in patients receiving vancomycin and concurrent and/or sequential systemic or topical use of other potentially neurotoxic and/or nephrotoxic drugs, such as amphotericin B, aminoglycosides, bacitracin, polymyxin B, colistin, viomycin, or cisplatin.

Pregnancy

Teratogenic Effects

Animal reproduction studies have not been conducted with vancomycin. It is not known whether vancomycin can affect reproduction capacity. In a controlled clinical study, the potential ototoxic and nephrotoxic effects of vancomycin on infants were evaluated when the drug was administered to pregnant women for serious staphylococcal infections complicating intravenous drug abuse. Vancomycin 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 attributed to the administration of vancomycin. Because the number of patients treated in this study was limited and vancomycin was administered only in the second and third trimesters, it is not known whether vancomycin causes fetal harm. Vancomycin should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Vancomycin is excreted in human milk. Caution should be exercised when vancomycin is administered to a nursing woman. Because of the potential for adverse events, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

In pediatric patients, it may be appropriate to confirm desired vancomycin serum concentrations. Concomitant administration of vancomycin and anesthetic agents has been associated with erythema and histamine-like flushing in pediatric patients (see PRECAUTIONS). The potential for toxic effects in pediatric patients from chemicals that may leach from the plastic containers into the single-dose, premixed intravenous preparation has not been determined.

Geriatric Use

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

Information for Patients

Severe Dermatologic Reactions

Advise patients about the signs and symptoms of serious skin manifestations. Instruct patients to stop Vancomycin Injection immediately and promptly seek medical attention at the first signs or symptoms of skin rash, mucosal lesions and blisters, (see **WARNINGS**).

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.

ADVERSE REACTIONS

Infusion-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 (“vancomycin infusion reaction”) 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

Systemic vancomycin exposure may result in acute kidney injury (AKI). The risk of AKI increases as systemic exposure/serum levels increase. Additional risk factors for AKI in patients receiving vancomycin include receipt of concomitant drugs known to be nephrotoxic, in patients with pre-existing renal impairment or with co-morbidities that predispose to renal impairment. Interstitial nephritis has also been reported in patients receiving vancomycin.

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 have been reported. Most of these patients had kidney dysfunction or a preexisting hearing loss or were receiving concomitant treatment with an ototoxic drug. 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 for several dozen patients. Neutropenia appears to be promptly reversible when vancomycin is discontinued. Thrombocytopenia has rarely been reported. Although a causal relationship has not been established, reversible agranulocytosis (granulocytes $<500/mm^3$) has been reported rarely.

Phlebitis

Inflammation at the injection site has been reported.

Miscellaneous

Patients have been reported to have had anaphylaxis, drug fever, nausea, chills, eosinophilia, rashes including exfoliative dermatitis, Stevens-Johnson syndrome (see WARNINGS, Severe Dermatologic Reactions), 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 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 drug exposure.

Skin and Subcutaneous Tissue Disorders

Severe dermatologic reactions such as toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP), and linear IgA bullous dermatosis (LABD) (see WARNINGS, Severe Dermatologic Reactions).

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 overdosage, consider the possibility of multiple drug overdoses, interaction among drugs, and unusual drug kinetics in your patient.

DOSAGE AND ADMINISTRATION

Vancomycin Injection, USP in the GALAXY plastic container is intended for intravenous use only.

Vancomycin in the GALAXY Container is not to be administered orally. An infusion rate of 10 mg/min or less is associated with fewer infusion-related events (see ADVERSE REACTIONS). Infusion related events may occur, however, at any rate or concentration.

Patients With Normal Renal Function

Adults

The usual daily intravenous 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, whichever is longer. Other patient factors, such as age or obesity, may call for modification of the usual intravenous daily dose.

Pediatric patients

The usual intravenous dosage of vancomycin is 10 mg/kg per dose given every 6 hours. Each dose should be administered over a period of at least 60 minutes. Close monitoring of serum concentrations of vancomycin may be warranted in these patients.

Neonates

In pediatric patients up to the age of 1 month, the total daily intravenous dosage may be lower. In neonates, an initial dose of 15 mg/kg is suggested, followed by 10 mg/kg every 12 hours for neonates in the 1st week of life and every 8 hours thereafter up to the age of 1 month. Each dose should be administered over 60 minutes. In premature infants, vancomycin clearance decreases as postconceptional age decreases. Therefore, longer dosing intervals may be necessary in premature infants. Close monitoring of serum concentrations of vancomycin is recommended in these patients.

Patients With Impaired Renal Function and Elderly Patients

Dosage adjustment must be made in patients with impaired renal function. In 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 seriously ill patients with changing renal function. Vancomycin serum concentrations can be determined by use of microbiologic assay, radioimmunoassay, fluorescence polarization immunoassay, fluorescence immunoassay, or high-pressure liquid chromatography. If creatinine clearance can be measured or estimated accurately, the dosage for most patients with renal impairment can be calculated using the following table. The dosage of vancomycin per day in mg is about 15 times the glomerular filtration rate in mL/min:

DOSAGE TABLE FOR VANCOMYCIN IN PATIENTS WITH IMPAIRED RENAL FUNCTION (Adapted from Moellering et al)[1]	
Creatinine Clearance mL/min	Vancomycin 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 initial dose should be no less than 15 mg/kg, even in patients with mild to 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 h. In patients with marked renal impairment, it may be more convenient to give maintenance doses of 250 to 1,000 mg once every several days rather than administering the drug on a daily basis. In anuria, a dose of 1,000 mg every 7 to 10 days has been recommended.

When only the serum creatinine concentration 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.

Men:	$\frac{\text{Weight (kg)} \times (140 - \text{age in years})}{72 \times \text{serum creatinine concentration (mg/dL)}}$
Women:	0.85 x above value

The serum creatinine must represent a steady state of renal function. Otherwise, the estimated value for creatinine clearance is not valid. Such a calculated clearance is an overestimate of actual clearance in patients with conditions: (1) characterized by decreasing renal function, such as shock, severe heart failure, or oliguria; (2) in which a normal relationship between muscle mass and total body weight is not present, such as obese patients or those with liver disease, edema, or ascites; and (3) accompanied by debilitation, malnutrition, or inactivity. The safety and efficacy of vancomycin administration by the intrathecal (intralumbar or intraventricular) routes have not been established.

Intermittent infusion is the recommended method of administration.

Directions for use of Vancomycin Injection, USP in GALAXY plastic container

Vancomycin Injection, USP in GALAXY plastic container is for intravenous administration

only.

Storage

Store in a freezer capable of maintaining a temperature at or below -20°C (-4°F).

Thawing of Plastic Containers:

1. Thaw frozen containers at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in waters baths or by microwave irradiation. **Do not force thaw.**
2. Check for minute leaks by squeezing the bag firmly. If leaks are detected, discard solution because sterility may be impaired.
3. Do not add supplemental medication.
4. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. Components of the solution may precipitate in the frozen state and will dissolve upon reaching room temperature with little or no agitation. Potency is not affected. Agitate after solution has reached room temperature. If after visual inspection the solution remains cloudy or if an insoluble precipitate is noted or if any seals are not intact, the container should be discarded.
5. The thawed solution in GALAXY plastic container remains chemically stable for 72 hours at room temperature (25°C/77°F) or for 30 days when stored under refrigeration (5°C/41°F).
6. **Do not refreeze thawed antibiotics.**

Preparation for Intravenous Administration:

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.
4. Use sterile equipment.

Caution: Do not use plastic containers in series connections. Such use could result in an embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is complete.

Rx only.

HOW SUPPLIED/STORAGE AND HANDLING

Vancomycin Injection, USP is supplied as a frozen, iso-osmotic, premixed solution in a 100 mL, 200 mL or 250 mL single-dose GALAXY plastic container in the following vancomycin doses in 5% Dextrose or 0.9% Sodium Chloride:

Vancomycin Injection, USP in 5% Dextrose		
2G3551	500 mg/100 mL (5 mg/mL) in single dose GALAXY container	NDC 0338-3551-48
2G3580	750 mg/150 mL (5 mg/mL) in single dose GALAXY container	NDC 0338-3580-48

2G3552	1 g/200 mL (5 mg/mL) in single dose GALAXY container	NDC 0338-3552-48
2G3557	1.25 g/250 mL (5 mg/mL) in single dose GALAXY container	NDC 0338-0122-04
2G3558	1.5 g/300 mL (5 mg/mL) in single dose GALAXY container	NDC 0338-0124-04

Vancomycin Injection, USP in 0.9% Sodium Chloride		
2G3590	500 mg/100 mL (5 mg/mL) in single dose GALAXY container	NDC 0338-3581-01
2G3591	750 mg/150 mL (5 mg/mL) in single dose GALAXY container	NDC 0338-3582-01
2G3592	1 g/200 mL (5 mg/mL) in single dose GALAXY container	NDC 0338-3583-01

Store at or below -20°C (-4°F).

See DIRECTIONS FOR USE OF Vancomycin Injection, USP in GALAXY plastic container.

The thawed solution in GALAXY plastic container remains chemically stable for 72 hours at room temperature (25°C/77°F) or for 30 days when stored under refrigeration (5°C/41°F). *Do not refreeze.* Handle frozen product containers with care. Product containers may be fragile in the frozen state.

ANIMAL PHARMACOLOGY

In animal studies, hypotension and bradycardia occurred in dogs receiving an intravenous infusion of vancomycin 25 mg/kg, at a concentration of 25 mg/mL and an infusion rate of 13.3 mL/min.

REFERENCES

1. Moellering RC, Krogstad DJ, Greenblatt DJ: Vancomycin therapy in patients with impaired renal function: A nomogram for dosage. *Ann Inter Med* 1981;94:343.

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PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 0338-3551-48

Vancomycin Injection, USP

in 5% Dextrose

500 mg per 100 mL
(5 mg/mL)

GALAXY
Single-Dose Container
Discard unused portion

Code 2G3551
Sterile Nonpyrogenic
Iso-osmotic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.

Cautions: Do not add supplementary medication or additives.

Rx Only

Store at or below -20°C (-4°F). Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw**. Thawed solution is stable for 30 days under refrigeration or 72 hours at room temperature. **Do not refreeze**.

PL 2040 Plastic

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Baxter Healthcare Corporation, Deerfield, IL 60015 USA

07-34-74-761

Container Label

NDC 0338-3551-48

Vancomycin Injection, USP
in 5% Dextrose

500 mg per 100 mL
(5 mg/mL)

GALAXY
Single-Dose Container
Discard unused portion

Code 2G3551
Sterile Nonpyrogenic
Iso-osmotic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or

sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.

Cautions: Do not add supplementary medication or additives.

Rx Only
Store at or below -20°C (-4°F). Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** Thawed solution is stable for 30 days under refrigeration or 72 hours at room temperature. **Do not refreeze**.

PL 2040 Plastic

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Baxter Healthcare Corporation, Deerfield, IL 60015 USA

07-34-74-761

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-74-764

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-74-764

Vancomycin Injection, USP in 5% Dextrose **Rx Only**

NDC 0338-3551-48
Code 2G3551

500 mg per 100 mL (5 mg/mL)

Contains 6 Single-Use bags. Each bag contains 100 mL. **Iso-osmotic Store at or below -20°C/-4°F.**

*FOR BAR CODE POSITION ONLY

(01) 20303383551485

Vancomycin Injection, USP in 5% Dextrose **Rx Only**

NDC 0338-3551-48
Code 2G3551

500 mg per 100 mL (5 mg/mL)

Contains 6 Single-Use bags. Each bag contains 100 mL. **Iso-osmotic Store at or below -20°C/-4°F.**

*FOR BAR CODE POSITION ONLY

(01) 20303383551485

GALAXY Container Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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GALAXY Container Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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Carton Label

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microware irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-74-764

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microware irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains

chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-74-764

Vancomycin Injection, USP in 5% Dextrose
500 mg per 100 mL (5 mg/ mL)
Contains 6 Single-Use bags. Each bag contains 100 mL. **Iso-osmotic. Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3551-48
Code 2G3551

*FOR BAR CODE POSITION ONLY
(01) 20303383551485

Vancomycin Injection, USP in 5% Dextrose
500 mg per 100 mL (5 mg/ mL)
Contains 6 Single-Use bags. Each bag contains 100 mL. **Iso-osmotic. Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3551-48
Code 2G3551

*FOR BAR CODE POSITION ONLY
(01) 20303383551485

GALAXY Container

Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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GALAXY Container

Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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NDC 0338-3552-48

Vancomycin Injection, USP

in 5% Dextrose

1 g per 200 mL
(5 mg/mL)

GALAXY
Single-Dose Container
Discard unused portion

Code 2G3552
Sterile Nonpyrogenic
Iso-osmotic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.

Cautions: Do not add supplementary medication or additives.

Rx Only

Store at or below -20°C (-4°F). Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw**. Thawed solution is stable for 30 days under refrigeration or 72 hours at room temperature. **Do not refreeze**.

PL 2040 Plastic

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07-34-74-763

Container Label

NDC 0338-3552-48

Vancomycin Injection, USP
in 5% Dextrose

1 g per 200 mL
(5 mg/mL)

GALAXY
Single-Dose Container
Discard unused portion

Code 2G3552
Sterile Nonpyrogenic
Iso-osmotic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.

Cautions: Do not add supplementary medication or additives.

Rx Only
Store at or below -20°C (-4°F). Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** Thawed solution is stable for 30 days under refrigeration or 72 hours at room temperature. **Do not refreeze**.

PL 2040 Plastic

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07-34-74-763

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-74-766

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-74-766

Vancomycin Injection, USP in 5% Dextrose **Rx Only**

NDC 0338-3552-48
Code 2G3552

1 g per 200 mL (5 mg/mL)

Contains 3 Single-Use bags. Each bag contains 200 mL. **Iso-osmotic Store at or below -20°C/-4°F.**

*FOR BAR CODE POSITION ONLY

(01) 20303383552482

Vancomycin Injection, USP in 5% Dextrose **Rx Only**

NDC 0338-3552-48
Code 2G3552

1 g per 200 mL (5 mg/mL)

Contains 3 Single-Use bags. Each bag contains 200 mL. **Iso-osmotic Store at or below -20°C/-4°F.**

*FOR BAR CODE POSITION ONLY

(01) 20303383552482

GALAXY Container Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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GALAXY Container Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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Carton Labels

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microware irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-74-766

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microware irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under

refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-74-766

Vancomycin Injection, USP in 5% Dextrose
1 g per 200 mL (5 mg/ mL)
Contains 3 Single-Use bags. Each bag contains 200 mL. **Iso-osmotic. Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3552-48
Code 2G3552

*FOR BAR CODE POSITION ONLY
(01) 20303383552482

Vancomycin Injection, USP in 5% Dextrose
1 g per 200 mL (5 mg/ mL)
Contains 3 Single-Use bags. Each bag contains 200 mL. **Iso-osmotic. Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3552-48
Code 2G3552

*FOR BAR CODE POSITION ONLY
(01) 20303383552482

GALAXY Container

Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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GALAXY Container

Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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NDC 0338-3580-48

Vancomycin Injection, USP

in 5% Dextrose

750 mg per 150 mL
(5 mg/mL)

GALAXY
Single-Dose Container
Discard unused portion

Code 2G3580
Sterile Nonpyrogenic
Iso-osmotic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.

Cautions: Do not add supplementary medication or additives.

Rx Only

Store at or below -20°C (-4°F). Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** Thawed solution is stable for 30 days under refrigeration or 72 hours at room temperature. **Do not refreeze.**

PL 2040 Plastic

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07-34-74-762

Container Label

NDC 0338-3580-48

Vancomycin Injection, USP
in 5% Dextrose

750 mg per 150 mL
(5 mg/mL)

GALAXY
Single-Dose Container

Discard unused portion

Code 2G3580
Sterile Nonpyrogenic
Iso-osmotic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.

Cautions: Do not add supplementary medication or additives.

Rx Only
Store at or below -20°C (-4°F). Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** Thawed solution is stable for 30 days under refrigeration or 72 hours at room temperature. **Do not refreeze**.

PL 2040 Plastic

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07-34-74-762

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**
Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-74-765

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**
Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-74-765

Vancomycin Injection, USP in 5% Dextrose **Rx Only**

NDC 0338-3580-48
Code 2G3580

750 mg per 150 mL (5 mg/mL)

Contains 3 Single-Use bags. Each bag contains 150 mL. **Iso-osmotic Store at or below -20°C/-4°F.**

*FOR BAR CODE POSITION ONLY

(01) 20303383580485

Vancomycin Injection, USP in 5% Dextrose **Rx Only**

NDC 0338-3580-48
Code 2G3580

750 mg per 150 mL (5 mg/mL)

Contains 3 Single-Use bags. Each bag contains 150 mL. **Iso-osmotic Store at or below -20°C/-4°F.**

*FOR BAR CODE POSITION ONLY

(01) 20303383580485

GALAXY Container Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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GALAXY Container Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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Carton Labels

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microware irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-74-765

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microware irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under

refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-74-765

Vancomycin Injection, USP in 5% Dextrose
750 mg per 150 mL (5 mg/ mL)
Contains 3 Single-Use bags. Each bag contains 150 mL. **Iso-osmotic. Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3580-48
Code 2G3580

*FOR BAR CODE POSITION ONLY
(01) 20303383580485

Vancomycin Injection, USP in 5% Dextrose
750 mg per 150 mL (5 mg/ mL)
Contains 3 Single-Use bags. Each bag contains 150 mL. **Iso-osmotic. Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3580-48
Code 2G3580

*FOR BAR CODE POSITION ONLY
(01) 20303383580485

GALAXY Container

Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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GALAXY Container

Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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NDC 0338-3581-01

Vancomycin Injection, USP

in 0.9% Sodium Chloride

500 mg per 100 mL

(5 mg/mL)

GALAXY
Single-Dose Container
Discard unused portion

Code 2G3590
Sterile Nonpyrogenic
Iso-osmotic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 0.9 g Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.

Cautions: Do not add supplementary medication or additives.

Rx Only

Store at or below -20°C (-4°F). Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw**. Thawed solution is stable for 30 days under refrigeration or 72 hours at room temperature. **Do not refreeze**.

PL 2040 Plastic

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07-34-74-548

Container Label

NDC 0338-3581-01

Vancomycin Injection, USP
in 0.9% Sodium Chloride

500 mg per 100 mL
(5 mg/mL)

GALAXY
Single-Dose Container
Discard unused portion

Code 2G3590
Sterile Nonpyrogenic
Iso-osmotic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 0.9 g Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.

Cautions: Do not add supplementary medication or additives.

Rx Only
Store at or below -20°C (-4°F). Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** Thawed solution is stable for 30 days under refrigeration or 72 hours at room temperature. **Do not refreeze**.

PL 2040 Plastic

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07-34-74-548

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-77-715

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-77-715

Vancomycin Injection, USP in 0.9% Sodium Chloride

500 mg per 100 mL (5 mg/mL)

Contains 6 Single-Dose bags. Each bag contains 100 mL. **Iso-osmotic Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3581-01
Code 2G3590

*FOR BAR CODE POSITION ONLY

(01) 20303383581017

Vancomycin Injection, USP in 0.9% Sodium Chloride

500 mg per 100 mL (5 mg/mL)

Contains 6 Single-Dose bags. Each bag contains 100 mL. **Iso-osmotic Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3581-01
Code 2G3590

*FOR BAR CODE POSITION ONLY

(01) 20303383581017

GALAXY Container

Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 0.9 g Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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GALAXY Container

Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 0.9 g Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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Carton Labels

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microware irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-77-715

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microware irradiation. **Do not**

force thaw. The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-77-715

Vancomycin Injection, USP in 0.9% Sodium Chloride
500 mg per 100 mL (5 mg/ mL)
Contains 6 Single-Dose bags. Each bag contains 100 mL. **Iso-osmotic. Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3581-01
Code 2G3590

*FOR BAR CODE POSITION ONLY
(01) 20303383581017

Vancomycin Injection, USP in 0.9% Sodium Chloride
500 mg per 100 mL (5 mg/ mL)
Contains 6 Single-Dose bags. Each bag contains 100 mL. **Iso-osmotic. Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3581-01
Code 2G3590

*FOR BAR CODE POSITION ONLY
(01) 20303383581017

GALAXY Container

Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 0.9 Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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GALAXY Container

Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 0.9 Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.

Cautions: Do not add supplementary medication or additives.

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NDC 0338-3582-01

Vancomycin Injection, USP

in 0.9% Sodium Chloride

750 mg per 150 mL
(5 mg/mL)

GALAXY
Single-Dose Container
Discard unused portion

Code 2G3591
Sterile Nonpyrogenic
Iso-osmotic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 0.9 g Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.

Cautions: Do not add supplementary medication or additives.

Rx Only

Store at or below -20°C (-4°F). Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** Thawed solution is stable for 30 days under refrigeration or 72 hours at room temperature. **Do not refreeze.**

PL 2040 Plastic

Baxter

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Baxter Healthcare Corporation, Deerfield, IL 60015 USA

07-34-74-551

Container Label

NDC 0338-3582-01

Vancomycin Injection, USP
in 0.9% Sodium Chloride

750 mg per 150 mL
(5 mg/mL)

GALAXY
Single-Dose Container
Discard unused portion

Code 2G3591
Sterile Nonpyrogenic
Iso-osmotic

Each 100 mL contains: Vancomycin Hydrochloride, USP

equivalent to 500 mg vancomycin with approx. 0.9 g Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.

Cautions: Do not add supplementary medication or additives.

Rx Only
Store at or below -20°C (-4°F). Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** Thawed solution is stable for 30 days under refrigeration or 72 hours at room temperature. **Do not refreeze**.

PL 2040 Plastic

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07-34-74-551

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-77-716

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-77-716

Vancomycin Injection, USP in 0.9% Sodium Chloride

750 mg per 150 mL (5 mg/mL)

Contains 3 Single-Dose bags. Each bag contains 150 mL. **Iso-osmotic Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3582-01
Code 2G3591

*FOR BAR CODE POSITION ONLY

(01) 20303383582014

Vancomycin Injection, USP in 0.9% Sodium Chloride

750 mg per 150 mL (5 mg/mL)

Contains 3 Single-Dose bags. Each bag contains 150 mL. **Iso-osmotic Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3582-01
Code 2G3591

*FOR BAR CODE POSITION ONLY

(01) 20303383582014

GALAXY Container Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 0.9 g Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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GALAXY Container Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 0.9 g Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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Carton Labels

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microware irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-77-715

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microware irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-77-715

Vancomycin Injection, USP in 0.9 Sodium Chloride
750 mg per 150 mL (5 mg/ mL)
Contains 3 Single-Dose bags. Each bag contains 150 mL. **Iso-osmotic. Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3582-01
Code 2G3591

*FOR BAR CODE POSITION ONLY
(01) 20303383582014

Vancomycin Injection, USP in 0.9 Sodium Chloride
750 mg per 150 mL (5 mg/ mL)
Contains 3 Single-Dose bags. Each bag contains 150 mL. **Iso-osmotic. Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3582-01
Code 2G3591

*FOR BAR CODE POSITION ONLY
(01) 20303383582014

GALAXY Container

Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 0.9 Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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GALAXY Container

Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 0.9 Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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NDC 0338-3583-01

Vancomycin Injection, USP

in 0.9% Sodium Chloride

1 g per 200 mL
(5 mg/mL)

GALAXY
Single-Dose Container
Discard unused portion

Code 2G3592
Sterile Nonpyrogenic
Iso-osmotic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 0.9 g Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.

Cautions: Do not add supplementary medication or additives.

Rx Only

Store at or below -20°C (-4°F). Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw**. Thawed solution is stable for 30 days under refrigeration or 72 hours at room temperature. **Do not refreeze**.

PL 2040 Plastic

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07-34-74-553

Container Label

NDC 0338-3583-01

Vancomycin Injection, USP
in 0.9% Sodium Chloride

1 g per 200 mL
(5 mg/mL)

GALAXY
Single-Dose Container
Discard unused portion

Code 2G3592
Sterile Nonpyrogenic
Iso-osmotic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 0.9 g Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.

Cautions: Do not add supplementary medication or additives.

Rx Only
Store at or below -20°C (-4°F). Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** Thawed solution is stable for 30 days under refrigeration or 72 hours at room temperature. **Do not refreeze**.

PL 2040 Plastic

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07-34-74-553

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-77-717

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). Product should not be thawed by immersion in water baths or by microwave irradiation. **Do not force thaw.** The thawed solution in GALAXY plastic container (PL 2040) remains chemically stable for 72 hours at room temperature or for 30 days when stored under refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-77-717

Vancomycin Injection, USP in 0.9% Sodium Chloride

1 g per 200 mL (5 mg/mL)

Contains 3 Single-Dose bags. Each bag contains 200 mL. **Iso-osmotic Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3583-01
Code 2G3592

*FOR BAR CODE POSITION ONLY

(01) 20303383583011

Vancomycin Injection, USP in 0.9% Sodium Chloride

1 g per 200 mL (5 mg/mL)

Contains 3 Single-Dose bags. Each bag contains 200 mL. **Iso-osmotic Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3583-01
Code 2G3592

*FOR BAR CODE POSITION ONLY

(01) 20303383583011

GALAXY Container Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 0.9 g Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additivies.

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GALAXY Container Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 0.9 g Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

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Carton Labels

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refrigeration. **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

PL 2040 Plastic 07-04-77-717

Vancomycin Injection, USP in 0.9 Sodium Chloride
1 g per 200 mL (5 mg/ mL)
Contains 3 Single-Dose bags. Each bag contains 200 mL. **Iso-osmotic. Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3583-01
Code 2G3592

*FOR BAR CODE POSITION ONLY
(01) 20303383583011

Vancomycin Injection, USP in 0.9 Sodium Chloride
1 g per 200 mL (5 mg/ mL)
Contains 3 Single-Dose bags. Each bag contains 200 mL. **Iso-osmotic. Store at or below -20°C/-4°F.**

Rx Only

NDC 0338-3583-01
Code 2G3592

*FOR BAR CODE POSITION ONLY
(01) 20303383583011

GALAXY Container

Sterile Nonpyrogenic

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 0.9 Sodium Chloride, USP in Water for Injection, USP. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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GALAXY Container

Sterile Nonpyrogenic

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Dosage: For intravenous use only. See prescribing information.
Cautions: Do not add supplementary medication or additives.

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NDC 0338-0122-04

1.25 g

Vancomycin Injection, USP

in 5% Dextrose

1.25 g per 250 mL (5 mg/mL)

For Intravenous Infusion Only
Single-Dose GALAXY Container
Discard Unused Portion

Rx Only
Sterile

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP.

Dosage: See prescribing information.

Store frozen at or below -20°C /-4°F.

Thaw at room temperature 20°C to 25°C (68°F to 77°F) or under refrigeration 2°C to 8°C (36°F to 46°F)
and store thawed solution as follows:

- Refrigerated Storage: Use within 30 days
- Room Temperature Storage: Use within 72 hours

Do not force thaw. Do not refreeze the thawed solution.
Do not add supplemental medication or additives.

Code 2G3557

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07-34-00-1841

Container Label

NDC 0338-0122-04

1.25 g

Vancomycin Injection, USP
in 5% Dextrose

1.25 g per 250 mL (5 mg/mL)

For Intravenous Infusion Only
Rx Only

Single-Dose GALAXY Container
Sterile
Discard Unused Portion

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP.
Dosage: See prescribing information.

Store frozen at or below -20°C /-4°F.

Thaw at room temperature 20°C to 25°C (68°F to 77°F) or under refrigeration 2°C to 8°C (36°F to 46°F)
and store thawed solution as follows:

– Refrigerated Storage: Use within 30 days
– Room Temperature Storage: Use within 72 hours

Do not force thaw. Do not refreeze the thawed solution.
Do not add supplemental medication or additives.

Code 2G3557

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Baxter Healthcare Corporation, Deerfield, IL 60015 USA

07-34-00-1841

*UPC-A BAR CODE
POSITION ONLY

309440495057

Store frozen at or below -20°C /-4°F. Thaw at room temperature 20°C to 25°C (68°F to 77°F) or under refrigeration 2°C to 8°C (36°F to 46°F) and store thawed solution as follows:
– Refrigerated Storage: Use within 30 days
– Room Temperature Storage: Use within 72 hours
Do not force thaw. Do not refreeze the thawed solution
Handle frozen product containers with care. Product containers may be fragile in the frozen state.
07-04-00-0961

1.25 g **Vancomycin Injection, USP** in 5% Dextrose
1.25 g per 250 mL (5 mg/mL)

For Intravenous Infusion Only.
Contains 2 units of Single-Dose bags.
Each bag contains 250 mL.
Store at or below -20°C/-4°F.

Rx Only NDC 0338-0122-04
Code 2G3557

*FOR BAR CODE POSITION ONLY
(01) 00000000000000

Store frozen at or below -20°C /-4°F. Thaw at room temperature 20°C to 25°C (68°F to 77°F) or under refrigeration 2°C to 8°C (36°F to 46°F) and store thawed solution as follows:
– Refrigerated Storage: Use within 30 days
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Do not force thaw. Do not refreeze the thawed solution
Handle frozen product containers with care. Product containers may be fragile in the frozen state.
07-04-00-0961

1.25 g **Vancomycin Injection, USP** in 5% Dextrose
1.25 g per 250 mL (5 mg/mL)

For Intravenous Infusion Only.
Contains 2 units of Single-Dose bags.
Each bag contains 250 mL.
Store at or below -20°C/-4°F.

Rx Only NDC 0338-0122-04
Code 2G3557

*FOR BAR CODE POSITION ONLY
(01) 00000000000000

GALAXY Container Sterile

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP.
Dosage: See prescribing information.
Do not add supplementary medication or additives.

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GALAXY Container Sterile

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP.
Dosage: See prescribing information.
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Carton Label

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– Refrigerated Storage: Use within 30 days
– Room Temperature Storage: Use within 72 hours

Do not force thaw. Do not refreeze the thawed solution
Handle frozen product containers with care. Product containers may be fragile in the frozen state.

07-04-00-0961

1.25 g

Vancomycin Injection, USP
in 5% Dextrose

1.25 g per 250 mL (5 mg/mL)

For Intravenous Infusion Only.

Contains 2 units of Single-Dose bags.
Each bag contains 250 mL.
Store at or below -20°C/-4°F.

Rx Only

NDC 0338-0122-04
Code 2G3557

*FOR BAR CODE POSITION ONLY
(01)00000000000000

GALAXY Container
Sterile

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP.

Dosage: See prescribing information.
Do not add supplementary medication or additives.

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NDC 0338-0124-04

1.5 g

Vancomycin Injection, USP

in 5% Dextrose

1.5 g per 300 mL (5 mg/mL)

For Intravenous Infusion Only
Single-Dose GALAXY Container
Discard Unused Portion

Rx Only
Sterile

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP.

Dosage: See prescribing information.

Store frozen at or below -20°C /-4°F.

Thaw at room temperature 20°C to 25°C (68°F to 77°F) or under refrigeration 2°C to 8°C (36°F to 46°F)
and store thawed solution as follows:

- Refrigerated Storage: Use within 30 days
- Room Temperature Storage: Use within 72 hours

Do not force thaw. Do not refreeze the thawed solution.
Do not add supplemental medication or additives.

Baxter

Code 2G3558

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07-34-00-1842

*UPC-A BAR CODE
POSITION ONLY

309440495057

Container Label

NDC 0338-0124-04

1.5 g

Vancomycin Injection, USP
in 5% Dextrose

1.5 g per 300 mL (5 mg/mL)

For Intravenous Infusion Only
Rx Only
Single-Dose GALAXY Container
Sterile
Discard Unused Portion

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP.
Dosage: See prescribing information.

Store frozen at or below -20°C /-4°F.

Thaw at room temperature 20°C to 25°C (68°F to 77°F) or under refrigeration 2°C to 8°C (36°F to 46°F)
and store thawed solution as follows:

– Refrigerated Storage: Use within 30 days
– Room Temperature Storage: Use within 72 hours

Do not force thaw. Do not refreeze the thawed solution.
Do not add supplemental medication or additives.

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Code 2G3558
07-34-00-1842

*UPC-A BAR CODE
POSITION ONLY

309440495057

Store frozen at or below -20°C /-4°F. Thaw at room temperature 20°C to 25°C (68°F to 77°F) or under refrigeration 2°C to 8°C (36°F to 46°F) and store thawed solution as follows:
– Refrigerated Storage: Use within 30 days
– Room Temperature Storage: Use within 72 hours
Do not force thaw. Do not refreeze the thawed solution
Handle frozen product containers with care. Product containers may be fragile in the frozen state.
07-04-00-0962

1.5 g **Vancomycin Injection, USP** in 5% Dextrose 1.5 g per 300 mL (5 mg/mL)

For Intravenous Infusion Only. Contains 2 units of Single-Dose bags. Each bag contains 300 mL. **Store at or below -20°C/-4°F.**

Rx Only NDC 0338-0124-04 Code 2G3558

*FOR BAR CODE POSITION ONLY

(01) 00000000000000

Store frozen at or below -20°C /-4°F. Thaw at room temperature 20°C to 25°C (68°F to 77°F) or under refrigeration 2°C to 8°C (36°F to 46°F) and store thawed solution as follows:
– Refrigerated Storage: Use within 30 days
– Room Temperature Storage: Use within 72 hours
Do not force thaw. Do not refreeze the thawed solution
Handle frozen product containers with care. Product containers may be fragile in the frozen state.
07-04-00-0962

1.5 g **Vancomycin Injection, USP** in 5% Dextrose 1.5 g per 300 mL (5 mg/mL)

For Intravenous Infusion Only. Contains 2 units of Single-Dose bags. Each bag contains 300 mL. **Store at or below -20°C/-4°F.**

Rx Only NDC 0338-0124-04 Code 2G3558

*FOR BAR CODE POSITION ONLY

(01) 00000000000000

GALAXY Container Sterile

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP.

Dosage: See prescribing information.
Do not add supplementary medication or additives.

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GALAXY Container Sterile

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP.

Dosage: See prescribing information.
Do not add supplementary medication or additives.

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Carton Label

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– Refrigerated Storage: Use within 30 days
– Room Temperature Storage: Use within 72 hours

Do not force thaw. Do not refreeze the thawed solution
Handle frozen product containers with care. Product containers may be fragile in the frozen state.

07-04-00-0962

1.5 g

Vancomycin Injection, USP
in 5% Dextrose

1.5 g per 300 mL (5 mg/mL)

For Intravenous Infusion Only.

Contains 2 units of Single-Dose bags.
Each bag contains 300 mL.
Store at or below -20°C/-4°F.

Rx Only

NDC 0338-0124-04
Code 2G3558

*FOR BAR CODE POSITION ONLY
(01)00000000000000

GALAXY Container
Sterile

Each 100 mL contains: Vancomycin Hydrochloride, USP equivalent to 500 mg vancomycin with approx. 5 g Dextrose Hydrous, USP in Water for Injection, USP.

Dosage: See prescribing information.
Do not add supplementary medication or additives.

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VANCOMYCIN HYDROCHLORIDE

vancomycin hydrochloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-3552
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VANCOMYCIN HYDROCHLORIDE (UNII: 71WO621TJD) (VANCOMYCIN - UNII:6Q205EH1VU)	VANCOMYCIN	1 g in 200 mL

Inactive Ingredients

Ingredient Name	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	10 g in 200 mL
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-3552-48	200 mL in 1 BAG; Type 0: Not a Combination Product	11/14/1958	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA050671	11/14/1958	

VANCOMYCIN HYDROCHLORIDE

vancomycin hydrochloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-3551
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VANCOMYCIN HYDROCHLORIDE (UNII: 71WO621TJD) (VANCOMYCIN - UNII:6Q205EH1VU)	VANCOMYCIN	500 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	5 g in 100 mL
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-3551-48	100 mL in 1 BAG; Type 0: Not a Combination Product	11/14/1958	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA050671	11/14/1958	

VANCOMYCIN HYDROCHLORIDE

vancomycin hydrochloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-3580
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VANCOMYCIN HYDROCHLORIDE (UNII: 71WO621TJD) (VANCOMYCIN - UNII:6Q205EH1VU)	VANCOMYCIN	750 mg in 150 mL

Inactive Ingredients

Ingredient Name	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	7.5 g in 150 mL
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-3580-48	200 mL in 1 BAG; Type 0: Not a Combination Product	11/14/1958	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA050671	11/14/1958	

VANCOMYCIN HYDROCHLORIDE

vancomycin hydrochloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-3581
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VANCOMYCIN HYDROCHLORIDE (UNII: 71WO621TJD) (VANCOMYCIN - UNII:6Q205EH1VU)	VANCOMYCIN	500 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.9 g in 100 mL
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:0338-3581-01	100 mL in 1 BAG; Type 0: Not a Combination Product	12/18/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA050671	11/14/1958	

VANCOMYCIN HYDROCHLORIDE

vancomycin hydrochloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-3582
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VANCOMYCIN HYDROCHLORIDE (UNII: 71WO621TJD) (VANCOMYCIN - UNII:6Q205EH1VU)	VANCOMYCIN	750 mg in 150 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	1.35 g in 150 mL
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-3582-01	150 mL in 1 BAG; Type 0: Not a Combination Product	12/18/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA050671	11/14/1958	

VANCOMYCIN HYDROCHLORIDE

vancomycin hydrochloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-3583
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VANCOMYCIN HYDROCHLORIDE (UNII: 71WO621TJD) (VANCOMYCIN - UNII:6Q205EH1VU)	VANCOMYCIN	1 g in 200 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	1.8 g in 200 mL
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-3583-01	200 mL in 1 BAG; Type 0: Not a Combination Product	12/18/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA050671	11/14/1958	

VANCOMYCIN HYDROCHLORIDE

vancomycin hydrochloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-0122
Route of Administration	INTRAVITREAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of	Strength

Ingredient Name	Strength	Strength
VANCOMYCIN HYDROCHLORIDE (UNII: 71WO621TJD) (VANCOMYCIN - UNII:6Q205EH1VU)	VANCOMYCIN	1.25 g in 250 mL

Inactive Ingredients

Ingredient Name	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	12.50 g in 250 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-0122-04	250 mL in 1 BAG; Type 0: Not a Combination Product	01/25/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA050671	11/14/1958	

VANCOMYCIN HYDROCHLORIDE

vancomycin hydrochloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-0124
Route of Administration	INTRAVITREAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VANCOMYCIN HYDROCHLORIDE (UNII: 71WO621TJD) (VANCOMYCIN - UNII:6Q205EH1VU)	VANCOMYCIN	1.50 g in 300 mL

Inactive Ingredients

Ingredient Name	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	15 g in 300 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-0124-04	300 mL in 1 BAG; Type 0: Not a Combination Product	01/25/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA050671	11/14/1958	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		194684502	ANALYSIS(0338-3552, 0338-3551, 0338-3580, 0338-3581, 0338-3582, 0338-3583, 0338-0122, 0338-0124) , MANUFACTURE(0338-3552, 0338-3551, 0338-3580, 0338-3581, 0338-3582, 0338-3583, 0338-0122, 0338-0124) , LABEL(0338-3552, 0338-3551, 0338-3580, 0338-3581, 0338-3582, 0338-3583, 0338-0122, 0338-0124) , PACK(0338-3552, 0338-3551, 0338-3580, 0338-3581, 0338-3582, 0338-3583, 0338-0122, 0338-0124) , STERILIZE(0338-3552, 0338-3551, 0338-3580, 0338-3581, 0338-3582, 0338-3583, 0338-0122, 0338-0124)

Revised: 1/2024 Baxter Healthcare Corporation