

# TYZAVAN- vancomycin injection, solution

## Hikma Pharmaceuticals USA Inc.

### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use TYZAVAN, safely and effectively. See full prescribing information for TYZAVAN.

TYZAVAN (vancomycin injection), for intravenous use  
Initial U.S. Approval: 1958

### RECENT MAJOR CHANGES

Boxed Warning	Removed 6/2025
Indications and Usage (1.1-1.5)	6/2025
Dosage and Administration (2.1, 2.3)	6/2025
Warnings and Precautions (5.1, 5.2)	6/2025

### INDICATIONS AND USAGE

TYZAVAN is a glycopeptide antibacterial indicated for the treatment of the following infections in adult and pediatric patients (1 month and older) for whom appropriate dosing with this formulation can be achieved:

- Septicemia (1.1)
- Infective Endocarditis (1.2)
- Skin and Skin Structure Infections (1.3)
- Bone Infections (1.4)
- Lower Respiratory Tract Infections (1.5)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of TYZAVAN and other antibacterial drugs, TYZAVAN should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria. (1.6)

### DOSAGE AND ADMINISTRATION

- If a dose of TYZAVAN is required that does not equal 500 mg, 750 mg, 1 g, 1.25 g, 1.5 g, 1.75 g or 2 g, this product is not recommended for use and an alternative formulation of vancomycin should be considered. (2.1)
- For intravenous use only. Do **not** administer orally (2.1).
- Administer TYZAVAN by intravenous infusion over 60 minutes or greater to reduce the risk of infusion reactions (2.1)
- Recommended Dosage in Adult Patients with Normal Renal Function: 2 g divided either as 0.5 grams (g) every 6 hours or 1 g every 12 hours (2.2)
- Recommended Dosage in Pediatric Patients (1 Month and Older) with Normal Renal Function: 10 mg/kg per dose given every 6 hours (2.3)
- Recommended Dosage in Patients with Renal Impairment: See full prescribing information for recommended doses in patients with renal impairment (2.4)
- See full prescribing information for further important preparation and administration instructions (2.1, 2.5)

### DOSAGE FORMS AND STRENGTHS

Injection: TYZAVAN contains 500 mg vancomycin in 100 mL, 750 mg vancomycin in 150 mL, 1 g vancomycin in 200 mL, 1.25 g vancomycin in 250 mL, 1.5 g vancomycin in 300 mL, 1.75 g vancomycin in 350 mL and 2 g vancomycin in 400 mL (5 mg/mL) of Water for Injection in single-dose flexible bags. (3)

### CONTRAINDICATIONS

Hypersensitivity to vancomycin (4)

### WARNINGS AND PRECAUTIONS

- Infusion Reactions: Hypotension, including shock and cardiac arrest, wheezing, dyspnea, urticaria, muscular and chest pain and “vancomycin infusion reactions” which manifests as pruritus and erythema that involves the face, neck and upper body may occur with rapid intravenous administration. To reduce the risk of infusion reactions, administer TYZAVAN over a period of 60 minutes or greater and also prior to intravenous anesthetic agents. (2.1, 5.1)

- Nephrotoxicity: Monitor renal function in all patients receiving TYZAVAN. (5.2)
- Ototoxicity: Serial tests of auditory function may be helpful. (5.3)
- Severe Dermatologic Reactions: Discontinue TYZAVAN at the first appearance of signs and symptoms of TEN, SJS, DRESS, AGEP, or LABD. (5.4)
- Clostridioides difficile-Associated Diarrhea (CDAD): Evaluate patients if diarrhea occurs. (5.5).
- Neutropenia: Periodically monitor leukocyte count. (5.7)
- Phlebitis and Other Administration Site Reactions: Vancomycin is irritating to tissue and must be given by a secure intravenous route of administration. (5.8)

#### -----ADVERSE REACTIONS-----

The most common adverse reactions are anaphylaxis, “vancomycin infusion reactions”, acute kidney injury, hearing loss, neutropenia. (6)

**To report SUSPECTED ADVERSE REACTIONS, contact Hikma Pharmaceuticals USA Inc. at 1-877-845-0689 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

#### -----DRUG INTERACTIONS-----

- Anesthetic Agents: Concomitant administration of vancomycin and anesthetic agents has been associated with erythema and histamine-like flushing. (2.1, 7.1)
- Piperacillin/Tazobactam: Increased incidence of acute kidney injury in patients receiving concomitant piperacillin/tazobactam and vancomycin as compared to vancomycin alone. Monitor kidney function in patients. (7.2)

**See 17 for PATIENT COUNSELING INFORMATION.**

**Revised: 8/2025**

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## **FULL PRESCRIBING INFORMATION**

### **1 INDICATIONS AND USAGE**

#### **1.1 Septicemia**

TYZAVAN is indicated in adults and pediatric patients (1 month and older) for whom appropriate dosing with this formulation can be achieved [see *Dosage and Administration (2) and Use in Specific Populations (8.4)*] for the treatment of septicemia due to:

- Susceptible isolates of methicillin-resistant *Staphylococcus aureus* (MRSA) and coagulase negative staphylococci.
- Methicillin-susceptible staphylococci in penicillin-allergic patients, or those patients who cannot receive or who have failed to respond to other drugs, including penicillins or cephalosporins.

## 1.2 Infective Endocarditis

TYZAVAN is indicated in adults and pediatric patients (1 month and older) for whom appropriate dosing with this formulation can be achieved [see *Dosage and Administration (2) and Use in Specific Populations (8.4)*] for the treatment of infective endocarditis due to:

- Susceptible isolates of MRSA.
- Viridans group streptococci *Streptococcus gallolyticus* (previously known as *Streptococcus bovis*), *Enterococcus* species and *Corynebacterium* species. For enterococcal endocarditis, use TYZAVAN in combination with an aminoglycoside.
- Methicillin-susceptible staphylococci in penicillin-allergic patients, or those patients who cannot receive or who have failed to respond to other drugs, including penicillins or cephalosporins.

TYZAVAN is indicated in adults and pediatric patients (1 month and older) for whom appropriate dosing with this formulation can be achieved [see *Dosage and Administration (2) and Use in Specific Populations (8.4)*] for the treatment of early-onset prosthetic valve endocarditis caused by *Staphylococcus epidermidis* in combination with rifampin and an aminoglycoside.

## 1.3 Skin and Skin Structure Infections

TYZAVAN is indicated in adults and pediatric patients (1 month and older) for whom appropriate dosing with this formulation can be achieved [see *Dosage and Administration (2) and Use in Specific Populations (8.4)*] for the treatment of skin and skin structure infections due to:

- Susceptible isolates of MRSA and coagulase negative staphylococci.
- Methicillin-susceptible staphylococci in penicillin-allergic patients, or those patients who cannot receive or who have failed to respond to other drugs, including penicillins or cephalosporins.

## 1.4 Bone Infections

TYZAVAN is indicated in adults and pediatric patients (1 month and older) for whom appropriate dosing with this formulation can be achieved [see *Dosage and Administration (2) and Use in Specific Populations (8.4)*] for the treatment of bone infections due to:

- Susceptible isolates of MRSA and coagulase negative staphylococci.
- Methicillin-susceptible staphylococci in penicillin-allergic patients, or those patients who cannot receive or who have failed to respond to other drugs, including penicillins or cephalosporins.

## 1.5 Lower Respiratory Tract Infections

TYZAVAN is indicated in adults and pediatric patients (1 month and older) for whom appropriate dosing with this formulation can be achieved [see *Dosage and Administration (2) and Use in Specific Populations (8.4)*] for the treatment of lower respiratory tract infections due to:

- Susceptible isolates of MRSA
- Methicillin-susceptible staphylococci in penicillin-allergic patients, or those patients who cannot receive or who have failed to respond to other drugs, including penicillins or cephalosporins.

## 1.6 Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of TYZAVAN and other antibacterial drugs, TYZAVAN 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.

## 2 DOSAGE AND ADMINISTRATION

### 2.1 Important Administration Instructions

- If a dose of TYZAVAN is required that does not equal 500 mg, 750 mg, 1 g, 1.25 g, 1.5 g, 1.75 g or 2 g, this product is not recommended for use and an alternative formulation of vancomycin should be considered.
  - TYZAVAN is intended for intravenous use only.
  - TYZAVAN is **not** to be administered orally.
  - To reduce the risk of infusion related adverse reactions, administer TYZAVAN by intravenous infusion over 60 minutes or greater [see *Warnings and Precautions (5.1)* and *Adverse Reactions (6.1)*]. An infusion rate of 10 mg/min or less is associated with fewer infusion-related adverse reactions [see *Warnings and Precautions (5.1)*]. Infusion related adverse reactions may occur, however, at any rate or concentration.
  - Drug additives should not be made to this solution.
  - TYZAVAN concentrations of no more than 5 mg/mL are recommended in adults and pediatric patients (1 month and older) [see *Dosage and Administration (2.2)*]. See also age-specific recommendations [see *Dosage and Administration (2.3)*].
  - Administer TYZAVAN by a secure intravenous route of administration to reduce the risk of local irritation and phlebitis reactions [see *Warnings and Precautions (5.8)*].
  - Administer TYZAVAN prior to intravenous anesthetic agents to reduce the risk of infusion related adverse reactions [see *Warnings and Precautions (5.1)*].

### 2.2 Recommended Dosage in Adult Patients with Normal Renal Function

The usual daily intravenous dosage of TYZAVAN is 2 grams (g) divided either as 500 mg every 6 hours or 1 g every 12 hours. Administer each dose by intravenous infusion over a period of 60 minutes or greater. Other patient factors, such as age or obesity, may call for modification of the usual intravenous daily dose. The initial daily dose should be no less than 15 mg/kg.

### 2.3 Recommended Dosage in Pediatric Patients (1 Month and Older) with Normal Renal Function

If a dose of TYZAVAN is required that does not equal 500 mg, 750 mg, 1 g, 1.25 g, 1.5 g, 1.75 g or 2 g, this product is not recommended for use and an alternative formulation of vancomycin should be considered [see *Use in Specific Populations (8.4)*].

## Pediatric Patients (Aged 1 Month and Older)

The usual intravenous dosage of TYZAVAN 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.

### **2.4 Recommended Dosage in Adult Patients with Renal Impairment**

Dosage adjustment must be made in adult patients with renal impairment. The initial dose of TYZAVAN should be no less than 15 mg/kg in patients with any degree of renal impairment.

In the elderly, greater dosage reductions than expected may be necessary because of decreased renal function. Measure trough vancomycin serum concentrations to guide therapy, especially in seriously ill patients with changing renal function.

For functionally anephric patients, an initial dose of 15 mg/kg of body weight should be given to achieve prompt therapeutic serum concentration. A dose of 1.9 mg/kg/24 h should be given after the initial dose of 15 mg/kg. Measure vancomycin serum concentrations at 24 hours following the first dose to guide further intravenous therapy.

### **2.5 Administration and Preparation and Storage Instructions for TYZAVAN**

#### Administration Instructions

TYZAVAN in transparent single-dose flexible bag is for intravenous administration only. Intermittent infusion is the recommended method of administration.

TYZAVAN is a room temperature stable, ready-to-use drug product.

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

#### Preparation for Intravenous Administration and Storage Instructions:

1. Remove the flexible bag from aluminum overpouch.
2. Check for minute leaks by squeezing the bag firmly. If leaks are detected, discard solution because sterility may be impaired. Leaks may be more readily detected by wrapping the bag with blotting paper or a tissue before squeezing.
3. Do not add supplemental medication.
4. Visually inspect the flexible bag. If the outlet port protector is damaged, detached, or not present, discard the flexible bag as solution path sterility may be impaired. If after visual inspection the solution is cloudy or if an insoluble precipitate is noted or if any seals are not intact, the flexible bag should be discarded.
5. The solution in the flexible bag remains chemically stable for 28 days at room temperature (15°C - 25°C (59°F - 77°F)) after removal from the aluminum overpouch. Discard unused drug.
6. Suspend the flexible bag from eyelet support.
7. Remove protector from outlet port at bottom of flexible bag.
8. Attach administration set. Refer to complete directions accompanying set.
9. Use sterile equipment.

Do **not** use flexible bags 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.

## **2.6 Incompatibilities for Intravenous Use**

Vancomycin solution has a low pH and may cause chemical or physical instability when it is mixed with other compounds.

Mixtures of solutions of vancomycin and beta-lactam antibacterial drugs have been shown to be physically incompatible. The likelihood of precipitation increases with higher concentrations of vancomycin. It is recommended to adequately flush the intravenous lines between the administration of these antibacterial drugs.

## **3 DOSAGE FORMS AND STRENGTHS**

Injection: TYZAVAN (Vancomycin Injection, USP) is a ready to use clear, colorless to light brown sterile solution in single-dose flexible bags in the following strengths: 500 mg vancomycin in 100 mL (5 mg/mL), 750 mg vancomycin in 150 mL (5 mg/mL), 1 g vancomycin in 200 mL (5 mg/mL), 1.25 g vancomycin in 250 mL (5 mg/mL), 1.5 g vancomycin in 300 mL (5 mg/mL), 1.75 g vancomycin in 350 mL (5 mg/mL) and 2 g vancomycin in 400 mL (5mg/mL) of Water for Injection [see *Description (11)*].

## **4 CONTRAINDICATIONS**

TYZAVAN is contraindicated in patients with known hypersensitivity to vancomycin.

## **5 WARNINGS AND PRECAUTIONS**

### **5.1 Infusion Reactions**

Hypotension, including shock and cardiac arrest, wheezing, dyspnea, urticaria or pruritus, muscular and chest pain may occur with rapid TYZAVAN administration (e.g., over several minutes). The reactions may be more severe in pediatric patients (1 month and older) [see *Use in Specific Populations (8.4)*].

Rapid intravenous administration of TYZAVAN may also be associated with “vancomycin infusion reactions” which manifests as pruritus and erythema that involves the face, neck and upper body or pain and muscle spasm of the chest and back. There have been reports that the frequency of of infusion-related reactions (including hypotension, flushing, erythema, urticaria, and pruritus) increases with the concomitant administration of anesthetic agents.

Infusion-related adverse reactions are related to both the concentration and the rate of administration of TYZAVAN. Infusion-related adverse reactions may occur, however, at any rate or concentration.

Administer TYZAVAN over a period of 60 minutes or greater to reduce the risk of infusion-related adverse reactions. 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 adverse reactions.

Administer TYZAVAN as a 60-minute infusion prior to administration of intravenous anesthetic agents when feasible to minimize infusion-related adverse reactions. Stop the infusion if a reaction occurs because this usually results in prompt cessation of these reactions.

## **5.2 Nephrotoxicity**

TYZAVAN can result in acute kidney injury (AKI), including acute renal failure, mainly due to interstitial nephritis or less commonly acute tubular necrosis. AKI is manifested by increasing blood urea nitrogen (BUN) and serum creatinine (Cr). The risk of AKI increases with higher vancomycin serum levels, prolonged exposure, concomitant administration of other nephrotoxic drugs, concomitant administration of piperacillin-tazobactam [see *Drug Interactions (7.2)*], volume depletion, pre-existing renal impairment and in critically ill patients and patients with co-morbid conditions that predispose to renal impairment.

Monitor serum vancomycin concentrations and renal function in all patients receiving TYZAVAN. More frequent monitoring is recommended in patients with comorbidities that predispose to impairment in renal function or are concomitantly receiving other nephrotoxic drugs, in critically ill patients, in patients with changing renal function, and in patients requiring higher therapeutic vancomycin levels. If acute kidney injury occurs, discontinue TYZAVAN or reduce the dose [see *Dosage and Administration (2.4)*].

## **5.3 Ototoxicity**

Ototoxicity has occurred in patients receiving vancomycin. It may be reversible or permanent. Ototoxicity manifests as tinnitus, hearing loss, dizziness or vertigo. The risk is higher in older patients, patients who are receiving higher doses, who have an underlying hearing loss, who are receiving concomitant therapy with another ototoxic agent, such as an aminoglycoside or who have underlying renal impairment. Monitor for signs and symptoms of ototoxicity during therapy. Monitor serum vancomycin concentrations and renal function in all patients receiving parenteral vancomycin. Discontinue TYZAVAN if ototoxicity occurs. Dosage of TYZAVAN must be adjusted for patients with renal impairment [see *Dosage and Administration (2.3)*]. Serial tests of auditory function may be helpful in order to minimize the risk of ototoxicity.

## **5.4 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 (including exfoliative dermatitis), mucosal lesions, and blisters.

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

## **5.5 *Clostridioides Difficile*-Associated Diarrhea (CDAD)**

*Clostridioides difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including vancomycin and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon

leading to overgrowth of *C. 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 antibacterial 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 antibacterial use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

Prolonged use of TYZAVAN 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.

### **5.6 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 the prophylaxis of endophthalmitis.

### **5.7 Neutropenia**

Reversible neutropenia has been reported in patients receiving vancomycin [see *Adverse Reactions (6.1)*]. 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.

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 been reported. Although a causal relationship has not been established, reversible agranulocytosis (granulocytes  $<500/\text{mm}^3$ ) has been reported.

### **5.8 Phlebitis and Other Administration Site Reactions**

Inflammation at the injection site has been reported. Vancomycin is irritating to tissue and must be given by a secure intravenous route of administration. 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.

Administration of TYZAVAN by intramuscular (IM), intraperitoneal, intrathecal (intralumbar or intraventricular), or intravitreal routes has not been approved and is not recommended. The safety and efficacy of vancomycin administered by these routes of administration have not been established by adequate and well controlled trials. Pain, tenderness, and necrosis occur with intramuscular (IM) injection of vancomycin or with

inadvertent extravasation. 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 of at least a 60-minute infusion prior to anesthetic induction.

Administration of sterile vancomycin by the intraperitoneal route during continuous ambulatory peritoneal dialysis (CAPD) has been reported to result in chemical peritonitis. Manifestations of this syndrome range from a cloudy dialysate alone to a cloudy dialysate accompanied by variable degrees of abdominal pain and fever. This syndrome appears to be resolved after discontinuation of intraperitoneal vancomycin.

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.

## **5.9 Development of Drug-Resistant Bacteria**

Prescribing TYZAVAN 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.

## **6 ADVERSE REACTIONS**

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Infusion Reactions [see *Warnings and Precautions (5.1)*]
- Nephrotoxicity [see *Warnings and Precautions (5.2)*]
- Ototoxicity [see *Warnings and Precautions (5.3)*]
- Severe Dermatologic Reactions [see *Warnings and Precautions (5.4)*]
- *Clostridioides Difficile*-Associated Diarrhea [see *Warnings and Precautions (5.5)*]
- Hemorrhagic Occlusive Retinal Vasculitis [see *Warnings and Precautions (5.6)*]
- Neutropenia [see *Warnings and Precautions (5.7)*]
- Phlebitis and Other Administration Site Reactions [see *Warnings and Precautions (5.8)*]

### **6.1 Clinical Trials Experience**

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The following adverse reactions associated with the use of vancomycin were identified in clinical trials:

*Immune System Disorders:* Anaphylaxis and “vancomycin infusion reaction”

*Renal and Urinary Disorders:* Acute kidney injury and interstitial nephritis

*Ear and Labyrinth Disorders:* Hearing loss, vertigo, and tinnitus

*Skin and Subcutaneous Tissue Disorders:* Rashes including exfoliative dermatitis, and

Stevens-Johnson syndrome (SJS)

*Gastrointestinal Disorders:* Clostridioides difficile colitis, nausea

*Blood and Lymphatic System Disorders:* Agranulocytosis, neutropenia, pancytopenia, leukopenia, thrombocytopenia, eosinophilia

*Cardiac Disorders:* Cardiac arrest, chest pain

*General Disorders and Administration Site Conditions:* General discomfort, fever, chills, phlebitis, injection site irritation, injection site pain and necrosis following intramuscular injection, chemical peritonitis following intraperitoneal administration (TYZAVAN is not approved for intramuscular and intraperitoneal administration)

*Laboratory Abnormalities:* Elevated blood urea nitrogen, elevated serum creatinine

*Musculoskeletal and Connective Tissue Disorders:* Muscle pain

*Nervous System Disorders:* Dizziness

*Respiratory, Thoracic and Mediastinal Disorders:* Wheezing, dyspnea

*Vascular Disorders:* Hypotension, shock, vasculitis

## **6.2 Postmarketing Experience**

The following adverse reactions have been identified during postmarketing 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.

*Immune System Disorders:* Acute myocardial ischemia with or without myocardial infarction may occur as part of an allergic reaction.

*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).

## **7 DRUG INTERACTIONS**

### **7.1 Anesthetic Agents**

Concomitant administration of vancomycin and anesthetic agents has been associated with erythema and histamine-like flushing [see *Warnings and Precautions (5.1) and Use in Specific Populations (8.4)*].

### **7.2 Piperacillin-Tazobactam**

Studies have detected an increased incidence of acute kidney injury in patients administered concomitant piperacillin/tazobactam and vancomycin as compared to vancomycin alone. Monitor kidney function in patients receiving concomitant piperacillin/tazobactam and TYZAVAN. No pharmacokinetic interactions have been noted between piperacillin/tazobactam and vancomycin.

### **7.3 Ototoxic and/or Nephrotoxic Drugs**

Concurrent and/or sequential systemic or topical use of other potentially neurotoxic and/or nephrotoxic drugs with TYZAVAN requires more frequent monitoring of renal function.

## **8 USE IN SPECIFIC POPULATIONS**

### **8.1 Pregnancy**

#### Risk Summary

The available data on the use of this formulation of TYZAVAN (which includes the excipient NADA) in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes (*see Data*). Available data over several decades of vancomycin (without the excipient NADA) use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes (*see Data*).

Vancomycin did not show adverse developmental effects when administered intravenously to pregnant rats and rabbits during organogenesis at doses less than or equal to the recommended maximum human dose (*see Data*).

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

#### Data

##### *Human Data*

Available data from postmarketing cases on use of this formulation of vancomycin injection (with the excipient NADA) in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or infant outcomes.

There are no available data on first trimester use of vancomycin (without the excipient NADA); however, available published data on use in pregnancy during the second and third trimesters have not shown an association with adverse pregnancy related outcomes.

A published study evaluated hearing loss and nephrotoxicity in infants of 10 pregnant intravenous drug users treated with intravenously administered vancomycin (formulation did not include the excipient NADA) for suspected or documented methicillin-resistant *Staphylococcus aureus* (MRSA) in the second or third trimester. The comparison groups were 10 non-intravenous drug-dependent patients who received no treatment, and 10 untreated intravenous drug-dependent patients who served as substance abuse controls. No infant in the vancomycin exposed group had abnormal sensorineural hearing at 3 months of age or nephrotoxicity.

A published prospective study assessed outcomes in 55 pregnant women with a positive Group B streptococcus (GBS) culture and a high-risk penicillin allergy with resistance to clindamycin or unknown sensitivity who were administered vancomycin (formulation did not include the excipient NADA) at the time of delivery. Vancomycin

dosing ranged from the standard 1 g intravenously every 12 hours to 20 mg/kg intravenous every 8 hours (maximum individual dose 2 g). No major adverse reactions were recorded either in the mothers or their newborns. None of the newborns had sensorineural hearing loss. Neonatal renal function was not examined, but all of the newborns were discharged in good condition.

### *Animal Data*

Vancomycin did not cause fetal malformations when administered during organogenesis to pregnant rats (gestation days 6 to 15) and rabbits (gestation days 6 to 18) at doses less than or equal to the recommended maximum human dose (based on body surface area comparisons) of 200 mg/kg/day IV to rats or 120 mg/kg/day IV to rabbits. No effects on fetal weight or development were seen in rats at the highest dose tested or in rabbits given 80 mg/kg/day (approximately 1 and 0.8 times the recommended maximum human dose based on body surface area, respectively). Maternal toxicity was observed in rats (at doses 120 mg/kg and above) and rabbits (at 80 mg/kg and above).<sup>1</sup>

Animal reproduction studies conducted in pregnant rabbits (gestation days 6 to 19) administered intravenous NADA at 1680 mg/kg (32 times the maximum daily human dose or greater based on AUC levels of NADA) resulted in fetal scoliosis and a spectrum of cardiovascular malformations. Increased incidence of delayed or incomplete ossifications of the metacarpals/metatarsals/phalanges and increased ossification (fused jugal/maxilla bones) were also observed in rabbits at 1680 mg/kg without maternal toxicity. No adverse developmental outcomes were observed in rabbits administered intravenous NADA at 560 mg/kg (11 times the maximum daily human dose based on AUC levels of NADA). In reproduction studies in pregnant rats (gestation days 6 to 17) administered intravenous NADA at 3780 mg/kg (20 times the maximum daily human dose based on AUC levels of NADA) no fetal adverse effects were observed. Maternal toxicity, including increased incidence of litter loss, was observed in rats at 3780 mg/kg [see *Clinical Pharmacology (12.3)*].

No animal studies have been conducted to evaluate the potential reproductive and embryo-fetal effects of TYZAVAN (with the excipient NADA).

## **8.2 Lactation**

### Risk Summary

Vancomycin is present in human milk following intravenous administration, however, there are insufficient data to inform the levels. There are no data on the effects of vancomycin on the breastfed infant or milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TYZAVAN and any potential adverse effects on the breastfed infant from TYZAVAN or from the underlying maternal condition.

## **8.4 Pediatric Use**

TYZAVAN is indicated in pediatric patients (1 month and older) for the treatment of septicemia, infective endocarditis, skin and skin structure infections, bone infections and lower respiratory tract infections for whom appropriate dosing with this formulation can be achieved [see *Indications and Usage (1.1 to 1.5) and Dosage and Administration (2.1, 2.3)*].

Because of the limitations of the available strengths and administration requirements

(i.e., administration of fractional doses is not recommended) of TYZAVAN, and to avoid unintentional overdose, this product is not recommended for use if a dose of TYZAVAN that does not equal 500 mg, 750 mg, 1 g, 1.25 g, 1.5 g, 1.75 g and 2 g is required, and an alternative formulation of vancomycin should be considered [see *Dosage and Administration (2.1, 2.3)*].

More severe infusion related reactions related to vancomycin administration may occur in pediatric patients. In pediatric patients, monitor vancomycin serum concentration and renal function when administering TYZAVAN [see *Dosage and Administration (2.3) and Warnings and Precautions (5.1)*]. Concomitant administration of vancomycin and intravenous anesthetic agents has been associated with erythema and histamine-like flushing in all patients including pediatric patients [see *Warnings and Precautions (5.1)*].

## 8.5 Geriatric Use

TYZAVAN is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection [see *Dosage and Administration (2.4)*], and it may be useful to monitor renal function [see *Warnings and Precautions (5.2)*].

## 8.6 Renal Impairment

Dosage adjustment of Vancomycin Injection must be made in patients with impaired renal function [see *Dosage and Administration (2.4)*]. Measure trough vancomycin serum concentrations to guide intravenous therapy, especially in patients with impaired renal function or fluctuating renal function.

## 10 OVERDOSAGE

Supportive care is advised, with maintenance of glomerular filtration. Vancomycin is poorly removed by dialysis.

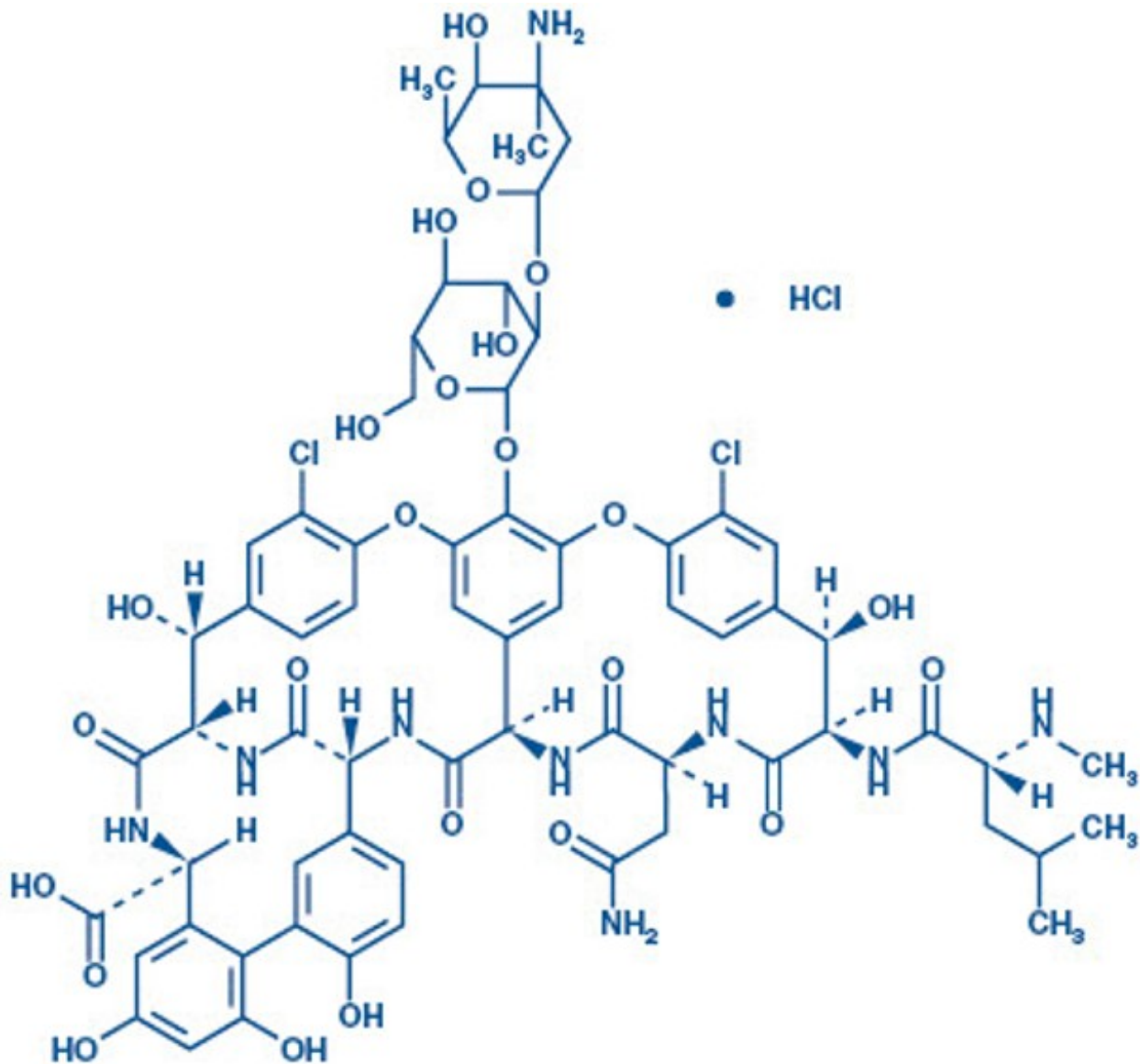
Hemofiltration and hemoperfusion with polysulfone resin have been reported to result in increased vancomycin clearance.

For current information on the management of overdose, contact the National Poison Control Center at 1-800-222-1222 or [www.poisson.org](http://www.poisson.org).

## 11 DESCRIPTION

TYZAVAN (Vancomycin Injection, USP), in single-dose flexible bags contain vancomycin as vancomycin hydrochloride. It is a tricyclic glycopeptide antibacterial drug derived from *Amycolatopsis orientalis* (formerly *Nocardia orientalis*). The chemical name is (*S<sub>a</sub>*)-(3*S*,6*R*,7*R*,22*R*,23*S*,26*S*,36*R*,38*aR*)-44-{[2-*O*-(3-amino-2,3,6-trideoxy-3-*C*-methyl- $\alpha$ -*L*-lyxo-hexopyranosyl)- $\beta$ -*D*-glucopyranosyl]-oxy}-3-(carbamoylmethyl)-10,19-dichloro-2,3,4,5,6,7,23,24,25,26,36,37,38,38*a*-tetradecahydro-7,22,28,30,32-pentahydroxy-6-[(2*R*)-4-methyl-2-(methylamino)valeramido]-2,5,24,38,39-pentaoxo-22*H*-8,11:18,21-dietheno-23,36(iminometha-no)-13,16:31,35-dimetheno-1*H*,16*H*-[1,6,9]-oxadiazacyclohexadecino-[4,5-*m*][10,2,16]-benzoxa-diazacyclotetracosine-26-carboxylic acid, monohydrochloride. The molecular formula is C<sub>66</sub>H<sub>75</sub>Cl<sub>2</sub>N<sub>9</sub>O<sub>24</sub>•HCl and the molecular weight is 1,485.71. Vancomycin hydrochloride has the following structural

formula:



TYZAVAN (Vancomycin Injection, USP), in single-dose flexible bags are sterile, nonpyrogenic premixed 100 mL, 150 mL, 200 mL, 250 mL, 300 mL, 350 mL or 400 mL solution containing 500 mg, 750 mg, 1 g, 1.25 g, 1.5 g, 1.75 g or 2 g vancomycin, respectively, as vancomycin hydrochloride. Each 100 mL of solution contains 1.36 g N-acetyl-D-alanine, 1.26 g L-lysine hydrochloride (monochloride) in water for injection. Hydrochloric acid and sodium hydroxide are used for pH adjustment. The pH is 4.5 to 5.5 and the osmolarity is 350 to 475 mOsmol/L.

## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

Vancomycin is an antibacterial drug [see Microbiology (12.4)].

### 12.2 Pharmacodynamics

Based on animal models of infection, the antimicrobial activity of vancomycin appears to correlate with the AUC/MIC (area under the concentration-time curve/minimum inhibitory concentration) ratio for certain pathogens, including methicillin resistant *Staphylococcus aureus*. The principal pharmacokinetic/pharmacodynamic parameter best associated with clinical and microbiological cure has not been elucidated in clinical trials <sup>2,3</sup>.

## **12.3 Pharmacokinetics**

### General Pharmacokinetics

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 those after a single dose.

In healthy subjects administered a single 1g dose of TYZAVAN, geometric mean (geometric %CV)  $AUC_{0-inf}$  values for NADA and vancomycin were 209 (19.6%) and 219 (13.7%) mcg\*h/mL, respectively. Based on a population pharmacokinetic analysis, 1g TYZAVAN administered over 1.5 hours every 12 hours achieves a geometric mean (95% prediction interval) steady state  $AUC_{0-24}$  exposure of 383 (277-547) and 382 (261-567) mcg\*h/mL for NADA and vancomycin in healthy subjects, respectively.

### Distribution

The distribution coefficient is from 0.3 to 0.43 L/kg. Vancomycin is approximately 55% serum protein bound as measured by ultrafiltration at vancomycin serum concentrations of 10 to 100 mcg/mL. After intravenous 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.

### Elimination

Mean plasma clearance is about 0.058 L/kg/h, and mean renal clearance is about 0.048 L/kg/h. The mean elimination half-life of vancomycin from plasma is 4 to 6 hours in subjects with normal renal function. In anephric patients, the mean elimination half-life is 7.5 days. Total systemic and renal clearance of vancomycin may be reduced in the elderly.

### *Metabolism*

There is no apparent metabolism of the vancomycin.

### *Excretion*

In the first 24 hours, about 75% of an administered dose of vancomycin is excreted in urine by glomerular filtration. Renal dysfunction slows excretion of vancomycin.

In the first 48 hours after intravenous administration of a single 1 g dose of TYZAVAN, the percent excreted unchanged in urine was approximately 80% for NADA.

## 12.4 Microbiology

### Mechanism of Action

The bactericidal action of vancomycin results primarily from inhibition of cell-wall biosynthesis. In addition, vancomycin alters bacterial-cell-membrane permeability and RNA synthesis.

### Resistance

There is no cross-resistance between vancomycin and other antibacterial(s). Vancomycin is not active *in vitro* against gram-negative bacilli, mycobacteria, or fungi.

### Interaction with Other Antimicrobials

The combination of vancomycin and an aminoglycoside acts synergistically *in vitro* against many isolates of *Staphylococcus aureus*, *Streptococcus gallolyticus* (previously known as *Streptococcus bovis*), *Enterococcus* spp, and the viridans group streptococci.

### Antimicrobial Activity

Vancomycin has been shown to be active against most isolates of the following bacteria, both *in vitro* and in clinical infections [see *Indications and Usage (1)*].

Aerobic bacteria

Gram-positive bacteria

*Corynebacterium* spp.

*Enterococcus* spp. (including *Enterococcus faecalis*)

*Staphylococcus aureus* (including methicillin-resistant and methicillin-susceptible isolates)

Coagulase negative staphylococci (including *S. epidermidis* and methicillin-resistant isolates)

*Streptococcus gallolyticus* (previously known as *Streptococcus bovis*)

Viridans group streptococci

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

At least 90 percent of the following bacteria exhibit an *in vitro* minimum inhibitory concentration (MIC) less than or equal to the susceptible breakpoint for vancomycin against isolates of similar genus or organism group. However, the efficacy of vancomycin in treating clinical infections caused by these bacteria has not been established in adequate and well-controlled clinical trials.

Aerobic bacteria

Gram-positive bacteria

*Listeria monocytogenes*

*Streptococcus pyogenes*

*Streptococcus pneumoniae*

*Streptococcus agalactiae*

Anaerobic bacteria

Gram-positive bacteria

*Actinomyces* spp.

*Lactobacillus* spp.

### Susceptibility Testing

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

## **13 NONCLINICAL TOXICOLOGY**

### **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

No long-term studies in animals have been performed to evaluate carcinogenic potential. No definitive fertility studies have been performed.

### **13.2 Animal Toxicology and/or 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.

## **15 REFERENCES**

1. Byrd RA., Gries CL, Buening M.: Developmental Toxicology Studies of Vancomycin Hydrochloride Administered Intravenously to Rats and Rabbits. *Fundam Appl Toxicol* 1994; 23: 590-597.
2. Rybak MJ. The pharmacokinetic and pharmacodynamic properties of vancomycin. *Clinical Infectious Diseases*. 2006;42(Supplement\_1): S35-S39.
3. Rybak MJ, Le J, Lodise TP, et al. Therapeutic monitoring of vancomycin for serious methicillin-resistant *Staphylococcus aureus* infections: a revised consensus guideline and review by the American Society of Health-System Pharmacists, the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, and the Society of Infectious Diseases Pharmacists. *Clinical Infectious Diseases*. 2020;71(6):1361-1364.

## **16 HOW SUPPLIED/STORAGE AND HANDLING**

### **16.1 How Supplied**

TYZAVAN (Vancomycin Injection, USP) is supplied as a ready to use clear, colorless to light brown solution in single-dose flexible bags containing 500 mg, 750 mg, 1 g, 1.25 g, 1.5 g, 1.75 g and 2 g vancomycin in 100 mL, 150 mL, 200 mL, 250 mL, 300 mL, 350 mL and 400 mL of liquid (consists of water for injection together with the excipients NADA and lysine) [see *Description (11)*]. The flexible bags are supplied in sealed aluminum

overpouches. The bags are supplied in the following packages described in table 1 below:

<b>Table 1: TYZAVAN PACKAGE INFORMATION</b>		
<b>Strength of TYZAVAN</b>	<b>NDC number</b>	<b>Packaging configuration</b>
500 mg/100 mL (5 mg/mL)	0143-9471-06	Carton of 6 bags
500 mg/100 mL (5 mg/mL)	0143-9471-12	Carton of 12 bags
750 mg/150 mL (5 mg/mL)	0143-9468-06	Carton of 6 bags
750 mg/150 mL (5 mg/mL)	0143-9468-12	Carton of 12 bags
1 g/200 mL (5 mg/mL)	0143-9472-06	Carton of 6 bags
1 g/200 mL (5 mg/mL)	0143-9472-12	Carton of 12 bags
1.25 g/250 mL (5 mg/mL)	0143-9466-06	Carton of 6 bags
1.5 g/300 mL (5 mg/mL)	0143-9469-06	Carton of 6 bags
1.75 g/350 mL (5 mg/mL)	0143-9467-06	Carton of 6 bags
2 g/400 mL (5 mg/mL)	0143-9470-06	Carton of 6 bags

## **16.2 Storage**

Store at 15°C to 25°C (59°F to 77°F), in original package. Use within 28 days of removal from aluminum overpouch.

## **17 PATIENT COUNSELING INFORMATION**

### Infusion Reactions During or After Intravenous Use

Advise patients that generalized skin redness, skin rash, itching, flushing, muscle pain, chest pain, shortness of breath, wheezing, or dizziness may occur during intravenous infusion of TYZAVAN. These reactions can be lessened or prevented by infusing the drug over at least 60 minutes [see *Warnings and Precautions (5.1)*].

### Acute Kidney Injury

Advise patients that TYZAVAN can result in kidney damage and that blood tests are required to monitor vancomycin blood levels and kidney function during therapy [see *Warnings and Precautions (5.2)*].

### Hearing Loss or Balance Problems

Advise patients that TYZAVAN may result in decreased hearing and to report hearing loss or balance problems to their healthcare provider [see *Warnings and Precautions (5.3)*].

### Severe Dermatologic Reactions

Advise patients about the signs and symptoms of serious skin manifestations. Instruct patients to stop TYZAVAN immediately and promptly seek medical attention at the first signs or symptoms of skin rash, mucosal lesions and blisters to their healthcare provider [see *Warnings and Precautions (5.4)*].

### Diarrhea

Diarrhea is a common problem caused by antibacterial drugs, including TYZAVAN, which

usually ends when the antibacterial drug is discontinued. Sometimes after starting treatment with antibacterial drugs, 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 antibacterial drug. If this occurs, patients should contact their physician as soon as possible [see *Warnings and Precautions (5.5)*].

### Antibacterial Resistance

Patients should be counseled that antibacterial drugs including TYZAVAN, should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When TYZAVAN 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 TYZAVAN or other antibacterial drugs in the future.

### **Manufactured for:**

Hikma Pharmaceuticals USA, Inc.

Berkeley Heights, NJ 07922

The logo for Hikma Pharmaceuticals, featuring the word "hikma." in a bold, lowercase, sans-serif font. The letters are black and the period is a solid black dot.

Made in Switzerland

L130USTZV01

### **PRINCIPAL DISPLAY PANEL - 500 mg/100 mL**

NDC 0143-9471-01

LOT

EXP

Rx Only

NEW

FORMULATION

TYZAVAN

(vancomycin injection, USP)

500 mg/100 mL (5 mg/mL)

Single-Dose Flexible Bag  
Sterile, Nonpyrogenic

Dosage: See Prescribing Information.

For Intravenous Use Only

Infuse over at least 60 minutes.

Cautions: Do not add supplementary medication or additives. Discard unused portion.

Store at 15°C to 25°C (59°F to 77°F), in original package.

Use within 28 days of removal from aluminum overpouch.

100 mL contains: Vancomycin hydrochloride equivalent to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride in water for injection.

pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Manufactured for Hikma Pharmaceuticals USA, Inc.  
Berkeley Heights, NJ 07922

500 mg

Ready  
To Use

NEW  
FORMULATION

Made in Switzerland  
BH130USTZV100

Rev. March 2025

Outlet port

XXYXXXXX      YYYY MMM

NDC 0143-9471-01      LOT      EXP      Rx Only

**NEW FORMULATION**

**TYZAVAN<sup>®</sup>**  
(vancomycin injection, USP)  
500 mg/100 mL (5 mg/mL)

Single-Dose Flexible Bag      Sterile, Nonpyrogenic

**Dosage:** See Prescribing Information.  
**For Intravenous Infusion Only**  
**Infuse over at least 60 minutes.**

**Cautions:** Do not add supplementary medication or additives. Discard unused portion.

**Store at 15°C to 25°C (59°F to 77°F), in original package.**  
Use within 28 days of removal from aluminum overpouch.

**100 mL contains:** Vancomycin hydrochloride equivalent to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride in water for injection. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.


Manufactured for **Hikma Pharmaceuticals USA, Inc.**  
Berkeley Heights, NJ 07922      Made in Switzerland  
Rev. July 2025      BH130USTZV101


**500 mg**

**Ready To Use**

**NEW FORMULATION**

Outlet port  
↓

  
101100301439471011



NDC 0143-9471-01

Rx Only

TYZAVAN

(vancomycin injection, USP)

500 mg/100 mL (5 mg/mL)

Single-Dose Flexible Bag

Sterile, Nonpyrogenic

**NEW FORMULATION**

**Ready To Use**

**Dosage:** See Prescribing Information.

**For Intravenous Infusion Only**

**Infuse over at least 60 minutes.**

**500 mg**

**Cautions:**

Do not add supplementary medication or additives. Discard unused portion.

Store at 15°C to 25°C (59°F to 77°F), in original package.

Use within 28 days of removal from aluminum overpouch.

100 mL contains: Vancomycin hydrochloride equivalent

to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride in water for injection. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Manufactured for Hikma Pharmaceuticals USA, Inc.  
Berkeley Heights, NJ 07922

Made in Switzerland

Rev. March 2025

Hikma

0130USTZV100

NDC 0143-9471-01 Rx Only

**TYZAVAN<sup>®</sup>**  
(vancomycin injection, USP)

**500 mg/100 mL (5 mg/mL)**

Single-Dose Flexible Bag Sterile, Nonpyrogenic

**NEW FORMULATION** Ready To Use

**Dosage:** See Prescribing Information.  
**For Intravenous Infusion Only**  
Infuse over at least 60 minutes.

**500 mg**

**Cautions:**  
Do not add supplementary medication or additives. Discard unused portion.

**Store at 15°C to 25°C (59°F to 77°F), in original package.**  
Use within 28 days of removal from aluminum overpouch.

**100 mL contains:** Vancomycin hydrochloride equivalent to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride in water for injection. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

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Berkeley Heights, NJ 07922  
Made in Switzerland  
Rev. March 2025

**hikma.**

3 01439 47101 1 0130USTZV100

LOT: XXXXXXX  
EXP: YYY MMM

**TYZAVAN<sup>®</sup>**  
(vancomycin injection, USP)  
**500 mg/100 mL**  
(5 mg/mL)

Rx Only  
Sterile

NDC 0143-9471-06  
Contains six (6) single-dose  
Flexible Bags of NDC 0143-9471-01

Ready

To Use

**TYZAVAN**

(vancomycin injection, USP)

500 mg/100 mL (5 mg/mL)

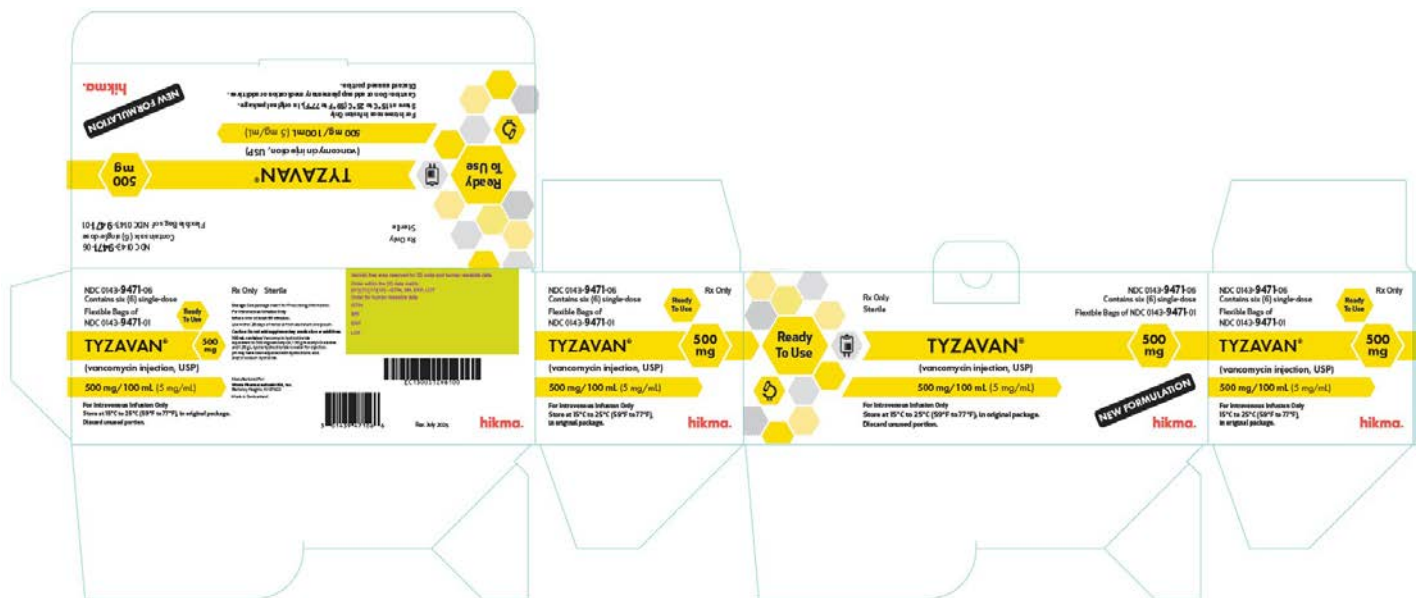
For Intravenous Use Only

Store at 15°F to 25°C (59°F to 77°F), in original package.

Discard unused portion.

500 mg

**NEW FORMULATION**



Rx Only

Sterile

NDC 0143-9471-12

Contains six (12) single-dose

Flexible Bags of NDC 0143-9471-01

Ready

To Use

**TYZAVAN**

(vancomycin injection, USP)

500 mg/100 mL (5 mg/mL)

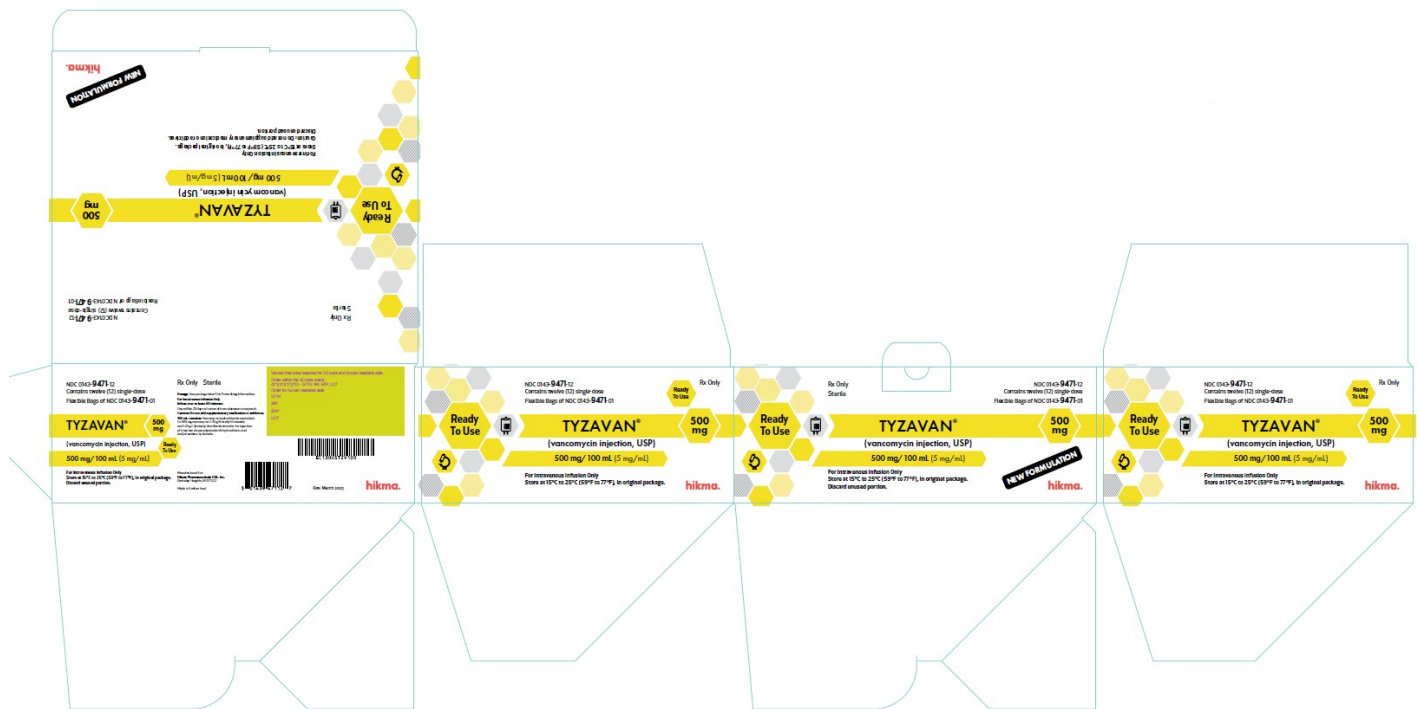
For Intravenous Infusion Only

Store at 15°F to 25°C (59°F to 77°F), in original package.

Discard unused portion.

500 mg

**NEW FORMULATION**



## PRINCIPAL DISPLAY PANEL - 750 mg/150 mL

NDC 0143-9468-01

EXP

Rx Only

NEW

FORMULATION

TYZAVAN

(vancomycin injection, USP)

750 mg/150 mL (5 mg/mL)

Single-Dose Flexible Bag

Sterile, Nonpyrogenic

Dosage: See Prescribing Information.

For Intravenous Infusion Only

Infuse over at least 60 minutes.

Cautions: Do not add supplementary medication or additives. Discard unused portion.

Store at 15°C to 25°C (59°F to 77°F), in original package.

Use within 28 days of removal from aluminum overpouch.

100 mL contains: Vancomycin hydrochloride equivalent

to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and

1.26 g L-lysine hydrochloride in water for injection.

pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Manufactured for Hikma Pharmaceuticals USA, Inc.

Berkeley Heights, NJ 07922

750 mg

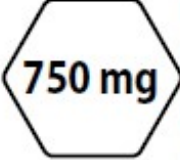


Ready  
To Use

NEW  
FORMULATION

Made in Switzerland  
BH130USTZV150

Rev. March 2025

Outlet port

XXYXXXXX		YYYY MMM	
LOT		EXP	
NDC 0143-9468-01		Rx Only	
<b>NEW FORMULATION</b>			
<b>TYZAVAN<sup>®</sup></b> (vancomycin injection, USP) <b>750 mg/ 150 mL (5 mg/mL)</b>			
Single-Dose Flexible Bag		Sterile, Nonpyrogenic	
<b>Dosage:</b> See Prescribing Information. <b>For Intravenous Infusion Only</b> <b>Infuse over at least 60 minutes.</b>			
<b>Cautions:</b> Do not add supplementary medication or additives. Discard unused portion.		<b>Ready To Use</b>	
<b>Store at 15°C to 25°C (59°F to 77°F), in original package.</b> Use within 28 days of removal from aluminum overpouch.			
<b>100 mL contains:</b> Vancomycin hydrochloride equivalent to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride in water for injection. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.			
Manufactured for <b>Hikma Pharmaceuticals USA, Inc.</b> Berkeley Heights, NJ 07922			
Made in Switzerland		<b>NEW FORMULATION</b>	
 101100301439468011		Rev. March 2025 BH130USTZV150	
<b>Outlet port</b> ↓			

NDC 0143-9468-01

Rx Only

TYZAVAN

(vancomycin injection, USP)

750 mg/150 mL (5 mg/mL)

Single-Dose Flexible Bag

Sterile, Nonpyrogenic

NEW FORMULATION

Ready To Use

Dosage: See Prescribing Information.

For Intravenous Infusion Only

Infuse over at least 60 minutes.

750 mg

Cautions:

Do not add supplementary medication  
or additives. Discard unused portion.

Store at 15°C to 25°C (59°F to 77°F), in original package.  
Use within 28 days of removal from aluminum overpouch.

100 mL contains: Vancomycin hydrochloride equivalent  
to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and  
1.26 g L-lysine hydrochloride in water for injection.  
pH may have been adjusted with hydrochloric acid  
and/or sodium hydroxide.

Manufactured for Hikma Pharmaceuticals USA, Inc.  
Berkeley Heights, NJ 07922

Made in Switzerland

Rev. March 2025

Hikma

0130USTZV150

NDC 0143-9468-01

Rx Only

**TYZAVAN<sup>®</sup>**

(vancomycin injection, USP)

**750 mg/ 150 mL (5 mg/mL)**

Single-Dose Flexible Bag

Sterile, Nonpyrogenic

**NEW FORMULATION**

Ready To Use

**Dosage:** See Prescribing Information.  
**For Intravenous Infusion Only**  
**Infuse over at least 60 minutes.**

**750 mg**

**Cautions:**

Do not add supplementary medication or additives. Discard unused portion.

**Store at 15°C to 25°C (59°F to 77°F), in original package.**  
Use within 28 days of removal from aluminum overpouch.

**100 mL contains:** Vancomycin hydrochloride equivalent to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride in water for injection. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.



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Berkeley Heights, NJ 07922  
Made in Switzerland  
Rev. March 2025



**hikma.**

O130USTZV150

**750 mg/ 150 mL**  
(5 mg/mL)

**TYZAVAN<sup>®</sup>**  
(vancomycin injection, USP)

LOT: XXXXXXXX

EXP.: YYYY MMMM

Rx Only  
Sterile

NDC 0143-9468-06  
Contains six (6) single-dose  
Flexible Bags of NDC 0143-9468-01

Ready  
To Use

TYZAVAN  
(vancomycin injection, USP)  
750 mg/150 mL (5 mg/mL)

For Intravenous Infusion Only  
Store at 15°F to 25°C (59°F to 77°F), in original package.  
Discard unused portion.

750  
mg

NEW FORMULATION



Rx Only  
Sterile

NDC 0143-9468-12  
Contains twelve (12) single-dose  
Flexible Bags of NDC 0143-9468-01

Ready  
To Use

TYZAVAN  
(vancomycin injection, USP)  
750 mg/150 mL (5 mg/mL)

For Intravenous Infusion Only  
Store at 15°F to 25°C (59°F to 77°F), in original package.  
Discard unused portion.

750  
mg

NEW FORMULATION

**PRINCIPAL DISPLAY PANEL - 1g/200mL**

NDC 0143-9472-01  
LOT

EXP  
Rx Only

NEW  
FORMULATION

TYZAVAN

(vancomycin injection, USP)  
1 g/200 mL (5 mg/mL)

Single-Dose Flexible Bag  
Sterile, Nonpyrogenic

Dosage: See Prescribing Information.

For Intravenous Infusion Only

Infuse over at least 60 minutes.

Cautions: Do not add supplementary medication or  
additives. Discard unused portion.

Store at 15°C to 25°C (59°F to 77°F), in original package.

Use within 28 days of removal from aluminum overpouch.

Each 100 mL contains: Vancomycin hydrochloride equivalent  
to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and  
1.26 g L-lysine hydrochloride in water for injection.  
pH may have been adjusted with hydrochloric acid  
and/or sodium hydroxide.

Manufactured for Hikma Pharmaceuticals USA, Inc.  
Berkeley Heights, NJ 07922

1 g

Ready  
To Use

NEW  
FORMULATION

Made in Switzerland  
BH130USTZV200

Rev. March 2025

Outlet port

XXYXXXXX

YYYY MMM

LOT

EXP

NDC 0143-9472-01

Rx Only

NEW  
FORMULATION**TYZAVAN<sup>®</sup>**  
(vancomycin injection, USP)  
**1 g/200 mL (5 mg/mL)**

Single-Dose Flexible Bag

Sterile, Nonpyrogenic

Dosage: See Prescribing Information.

For Intravenous Infusion Only

Infuse over at least 60 minutes.

Cautions: Do not add supplementary medication  
or additives. Discard unused portion.Store at 15°C to 25°C (59°F to 77°F), in original package.  
Use within 28 days of removal from aluminum overpouch.Each 100 mL contains: Vancomycin hydrochloride equivalent to  
500 mg vancomycin; 1.36 g N-acetyl-D-alanine and  
1.26 g L-lysine hydrochloride in water for injection. pH may have been  
adjusted with hydrochloric acid and/or sodium hydroxide.Manufactured for Hikma Pharmaceuticals USA, Inc.  
Berkeley Heights, NJ 07922

Made in Switzerland

NEW  
FORMULATION

Rev. March 2025

BH130USTZV200



101100301439472018



Outlet port



NDC 0143-9472-01

Rx Only

TYZAVAN

(vancomycin injection, USP)

1 g/200 mL (5 mg/mL)

Single-Dose Flexible Bag

Sterile, Nonpyrogenic

NEW FORMULATION

Ready To Use

Dosage: See Prescribing Information.  
For Intravenous Infusion Only  
Infuse over at least 60 minutes.

1 g

Cautions:

Do not add supplementary medication  
or additives. Discard unused portion.

Store at 15°C to 25°C (59°F to 77°F), in original package.  
Use within 28 days of removal from aluminum overpouch.

Each 100 mL contains: Vancomycin hydrochloride equivalent  
to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and  
1.26 g L-lysine hydrochloride in water for injection.  
pH may have been adjusted with hydrochloric acid  
and/or sodium hydroxide.

Manufactured for Hikma Pharmaceuticals USA, Inc.  
Berkeley Heights, NJ 07922

Made in Switzerland  
Rev. March 2025

Hikma

O130USTZV200

NDC 0143-9472-01

Rx Only

**TYZAVAN<sup>®</sup>**

(vancomycin injection, USP)

**1 g/200 mL (5 mg/mL)**

Single-Dose Flexible Bag

Sterile, Nonpyrogenic

**NEW FORMULATION**

Ready To Use

**Dosage:** See Prescribing Information.

**For Intravenous Infusion Only**

**Infuse over at least 60 minutes.**

**1 g**

**Cautions:**

Do not add supplementary medication or additives. Discard unused portion.

**Store at 15°C to 25°C (59°F to 77°F), in original package.** Use within 28 days of removal from aluminum overpouch.

**Each 100 mL contains:** Vancomycin hydrochloride equivalent to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride in water for injection. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.



Manufactured for **Hikma Pharmaceuticals USA, Inc.**  
Berkeley Heights, NJ 07922  
Made in Switzerland  
Rev. March 2025



3 01439 47201 8

**hikma.**

O130USTZV200

**1 g/200 mL**  
(5 mg/mL)

**TYZAVAN<sup>®</sup>**  
(vancomycin injection, USP)

LOT: XXXXXXXX

EXP.: YYY MMM

Rx Only  
Sterile

NDC 0143-9472-06  
Contains six (6) single-dose  
Flexible Bags of NDC 0143-9472-01

Ready  
To Use

TYZAVAN  
(vancomycin injection, USP)  
1 g/200 mL (5 mg/mL)

For Intravenous Infusion Only  
Store at 15°F to 25°C (59°F to 77°F), in original package.  
Discard unused portion.

1 g

NEW FORMULATION



Rx Only  
Sterile

NDC 0143-9472-12  
Contains twelve (12) single-dose  
Flexible Bags of NDC 0143-9472-01

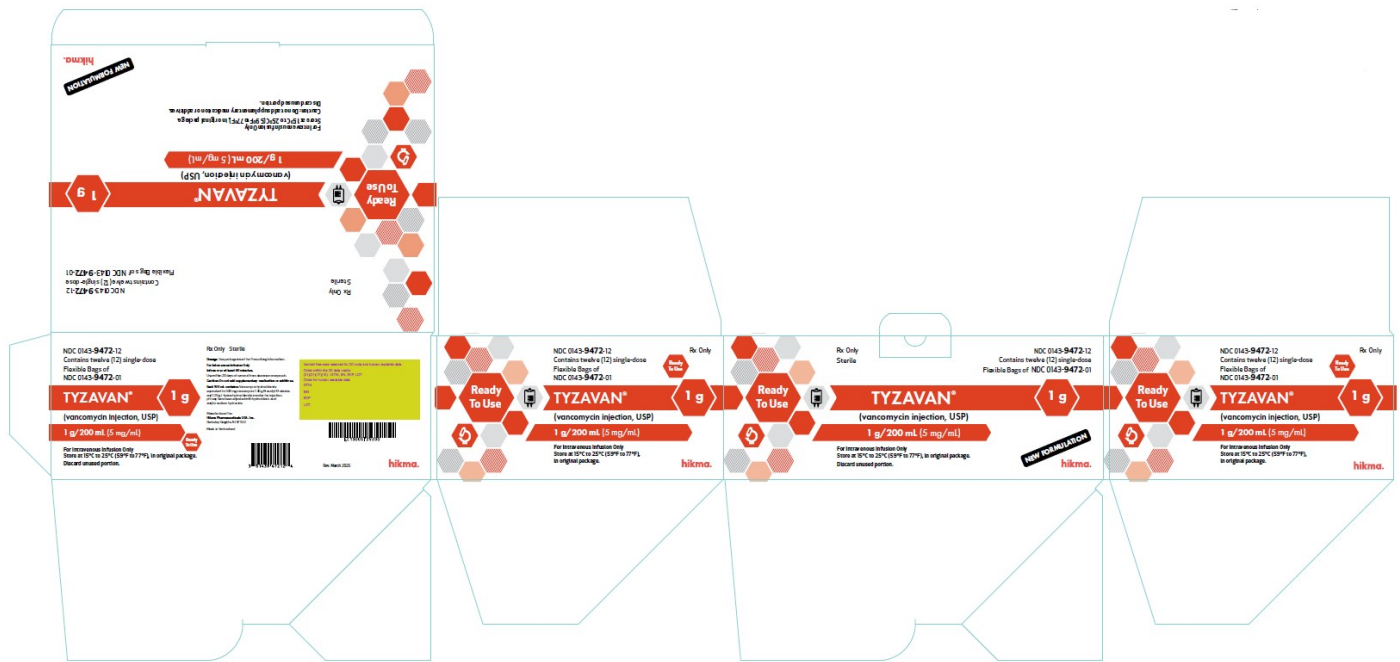
Ready  
To Use

TYZAVAN  
(vancomycin injection, USP)  
1 g/200 mL (5 mg/mL)

For Intravenous Infusion Only  
Store at 15°F to 25°C (59°F to 77°F), in original package.  
Discard unused portion.

1 g

NEW FORMULATION



## PRINCIPAL DISPLAY PANEL - 1.25g/250mL

NDC 0143-9466-01

LOT

EXP

Rx Only

NEW

FORMULATION

TYZAVAN

(vancomycin injection, USP)

1.25 g/250 mL (5 mg/mL)

Single-Dose Flexible Bag  
Sterile, Nonpyrogenic

Dosage: See Prescribing Information.

For Intravenous Infusion Only

Infuse over at least 60 minutes.

Cautions: Do not add supplementary medication or additives. Discard unused portion.

Store at 15°C to 25°C (59°F to 77°F), in original package.

Use within 28 days of removal from aluminum overpouch.

Each 100 mL contains: Vancomycin hydrochloride equivalent to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride in water for injection. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Manufactured for Hikma Pharmaceuticals USA, Inc.  
Berkeley Heights, NJ 07922

1.25 g

Ready  
To Use

NEW  
FORMULATION

Made in Switzerland  
BH130USTZV250

Rev. March 2025

Outlet port

XXXXXXXXXX      YYYY MMM

LOT      EXP

NDC 0143-9466-01      Rx Only

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**NEW FORMULATION**

**TYZAVAN<sup>®</sup>**  
(vancomycin injection, USP)  
**1.25 g/250 mL (5 mg/mL)**

---

Single-Dose Flexible Bag      Sterile, Nonpyrogenic

**Dosage:** See Prescribing Information.  
**For Intravenous Infusion Only**  
**Infuse over at least 60 minutes.**

**Cautions:** Do not add supplementary medication or additives. Discard unused portion.

**Store at 15°C to 25°C (59°F to 77°F), in original package.**  
Use within 28 days of removal from aluminum overpouch.

**Each 100 mL contains:** Vancomycin hydrochloride equivalent to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride in water for injection. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Manufactured for **Hikma Pharmaceuticals USA, Inc.**  
Berkeley Heights, NJ 07922

Made in Switzerland

**1.25 g**


**Ready To Use**

**NEW FORMULATION**

Rev. March 2025  
BH130USTZV250

101100301439466017

Outlet port  
↓



NDC 0143-9466-01

Rx Only

TYZAVAN

(vancomycin injection, USP)

1.25 g/250 mL (5 mg/mL)

Single-Dose Flexible Bag

Sterile, Nonpyrogenic

NEW FORMULATION

Ready To Use

Dosage: See Prescribing Information.

For Intravenous Infusion Only

Infuse over at least 60 minutes.

1.25 g

Cautions:

Do not add supplementary medication  
or additives. Discard unused portion.

Store at 15°C to 25°C (59°F to 77°F), in original package.

Use within 28 days of removal from aluminum overpouch.

Each 100 mL contains: Vancomycin hydrochloride equivalent  
to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and  
1.26 g L-lysine hydrochloride in water for injection.  
pH may have been adjusted with hydrochloric acid  
and/or sodium hydroxide.

Manufactured for Hikma Pharmaceuticals USA, Inc.

Berkeley Heights, NJ 07922

Made in Switzerland

Rev. March 2025

Hikma

0130USTZV250

NDC 0143-9466-01

Rx Only

**TYZAVAN<sup>®</sup>**

(vancomycin injection, USP)

**1.25 g/250 mL (5 mg/mL)**

Single-Dose Flexible Bag

Sterile, Nonpyrogenic

**NEW FORMULATION**

**Ready To Use**

**Dosage:** See Prescribing Information.

**For Intravenous Infusion Only**

**Infuse over at least 60 minutes.**

**1.25 g**

**Cautions:**

Do not add supplementary medication or additives. Discard unused portion.

**Store at 15°C to 25°C (59°F to 77°F), in original package.** Use within 28 days of removal from aluminum overpouch.

**Each 100 mL contains:** Vancomycin hydrochloride equivalent to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride in water for injection. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.



Manufactured for **Hikma Pharmaceuticals USA, Inc.**  
Berkeley Heights, NJ 07922  
Made in Switzerland  
Rev. March 2025



**hikma.**

O130USTZV250

LOT: XXXXXXXX

EXP.: WYY MMM

**1.25 g/250 mL**  
(5 mg/mL)

**TYZAVAN<sup>®</sup>**  
(vancomycin injection, USP)

Rx Only  
Sterile

NDC 0143-9466-06  
Contains six (6) single-dose  
Flexible Bags of NDC 0143-9466-01

Ready  
To Use

TYZAVAN  
(vancomycin injection, USP)  
1.25 g/250 mL (5 mg/mL)

For Intravenous Infusion Only  
Store at 15°F to 25°C (59°F to 77°F), in original package.  
Discard unused portion.

1.25 g

# NEW FORMULATION



## PRINCIPAL DISPLAY PANEL - 1.5g/300mL

NDC 0143-9469-01

LOT

EXP

Rx Only

NEW  
FORMULATION

**TYZAVAN**  
(vancomycin injection, USP)  
1.5 g/300 mL (5 mg/mL)

Single-Dose Flexible Bag  
Sterile, Nonpyrogenic

Dosage: See Prescribing Information.

For Intravenous Infusion Only

Infuse over at least 60 minutes.

Cautions: Do not add supplementary medication or additives. Discard unused portion.

Store at 15°C to 25°C (59°F to 77°F), in original package.

Use within 28 days of removal from aluminum overpouch.

Each 100 mL contains: Vancomycin hydrochloride equivalent to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride in water for injection.

pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Manufactured for Hikma Pharmaceuticals USA, Inc.  
Berkeley Heights, NJ 07922

1.5 g

Ready  
To Use

NEW  
FORMULATION

Made in Switzerland  
BH130USTZV300

Rev. March 2025

Outlet port

XXYXXXXX

YYYY MMM

LOT

EXP

NDC 0143-9469-01

Rx Only

NEW  
FORMULATION

**TYZAVAN<sup>®</sup>**  
 (vancomycin injection, USP)  
 1.5 g/300 mL (5 mg/mL)

Single-Dose Flexible Bag

Sterile, Nonpyrogenic

**Dosage:** See Prescribing Information.  
**For Intravenous Infusion Only**  
 Infuse over at least 60 minutes.

**Cautions:** Do not add supplementary medication  
 or additives. Discard unused portion.

**Store at 15°C to 25°C (59°F to 77°F), in original package.**  
 Use within 28 days of removal from aluminum overpouch.

**Each 100 mL contains:** Vancomycin hydrochloride equivalent to  
 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride  
 in water for injection. pH may have been adjusted with hydrochloric acid  
 and/or sodium hydroxide.

Manufactured for **Hikma Pharmaceuticals USA, Inc.**  
 Berkeley Heights, NJ 07922

Made in Switzerland

NEW  
FORMULATIONRev. March 2025  
BH130USTZV300

Outlet port



NDC 0143-9469-01

Rx Only

TYZAVAN  
 (vancomycin injection, USP)  
 1.5 g/300 mL (5 mg/mL)

Single-Dose Flexible Bag  
 Sterile, Nonpyrogenic

NEW FORMULATION  
 Ready To Use

Dosage: See Prescribing Information.  
For Intravenous Infusion Only  
Infuse over at least 60 minutes.

1.5 g

Cautions:

Do not add supplementary medication  
or additives. Discard unused portion.

Store at 15°C to 25°C (59°F to 77°F), in original package.  
Use within 28 days of removal from aluminum overpouch.

Each 100 mL contains: Vancomycin hydrochloride equivalent  
to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and  
1.26 g L-lysine hydrochloride in water for injection.  
pH may have been adjusted with hydrochloric acid  
and/or sodium hydroxide.

Manufactured for Hikma Pharmaceuticals USA, Inc.  
Berkeley Heights, NJ 07922

Made in Switzerland  
Rev. March 2025

Hikma

0130USTZV300

NDC 0143-9469-01

Rx Only

**TYZAVAN<sup>®</sup>**

(vancomycin injection, USP)

**1.5 g/300 mL (5 mg/mL)**

Single-Dose Flexible Bag

Sterile, Nonpyrogenic

**NEW FORMULATION**

Ready To Use

**Dosage:** See Prescribing Information.

**For Intravenous Infusion Only**

**Infuse over at least 60 minutes.**

**1.5 g**

**Cautions:**

Do not add supplementary medication or additives. Discard unused portion.

**Store at 15°C to 25°C (59°F to 77°F), in original package.**

Use within 28 days of removal from aluminum overpouch.

**Each 100 mL contains:** Vancomycin hydrochloride equivalent to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride in water for injection. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.



Manufactured for **Hikma Pharmaceuticals USA, Inc.**

Berkeley Heights, NJ 07922

Made in Switzerland

Rev. March 2025



**hikma.**

0130USTZV300

LOT: XXXXXXXX

EXP.: YYY MMM

**1.5 g/300 mL**  
(5 mg/mL)

**TYZAVAN<sup>®</sup>**  
(vancomycin injection, USP)

Rx Only

Sterile

NDC 0143-9469-06

Contains six (6) single-dose

Flexible Bags of NDC 0143-9469-01

Ready

To Use

TYZAVAN

(vancomycin injection, USP)

1.5 g/300 mL (5 mg/mL)

For Intravenous Infusion Only

Store at 15°F to 25°C (59°F to 77°F), in original package.

Discard unused portion.

1.5 g

# NEW FORMULATION



## PRINCIPAL DISPLAY PANEL - 1.75g/350mL

NDC 0143-9467-01

LOT

EXP

Rx Only

NEW  
FORMULATION

TYZAVAN

(vancomycin injection, USP)

1.75 g/350 mL (5 mg/mL)

Single-Dose Flexible Bag  
Sterile, Nonpyrogenic

Dosage: See Prescribing Information.

For Intravenous Infusion Only

Infuse over at least 60 minutes.

Cautions: Do not add supplementary medication or additives. Discard unused portion.

Store at 15°C to 25°C (59°F to 77°F), in original package.

Use within 28 days of removal from aluminum overpouch.

Each 100 mL contains: Vancomycin hydrochloride equivalent to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and

1.26 g L-lysine hydrochloride in water for injection.

pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Manufactured for Hikma Pharmaceuticals USA, Inc.  
Berkeley Heights, NJ 07922

1.75 g

Ready  
To Use

NEW  
FORMULATION

Made in Switzerland  
BH130USTZV350

Rev. March 2025

Outlet port

XXYXXXXX

YYYY MMM

LOT

EXP

NDC 0143-9467-01

Rx Only

**NEW  
FORMULATION****TYZAVAN<sup>®</sup>**  
(vancomycin injection, USP)  
**1.75 g/350 mL (5 mg/mL)**

Single-Dose Flexible Bag

Sterile, Nonpyrogenic

**Dosage:** See Prescribing Information.  
**For Intravenous Infusion Only**  
**Infuse over at least 60 minutes.****Cautions:** Do not add supplementary medication  
or additives. Discard unused portion.**Store at 15°C to 25°C (59°F to 77°F), in original package.**  
Use within 28 days of removal from aluminum overpouch.**Each 100 mL contains:** Vancomycin hydrochloride equivalent to  
500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride  
in water for injection. pH may have been adjusted with hydrochloric acid  
and/or sodium hydroxide.Manufactured for **Hikma Pharmaceuticals USA, Inc.**  
Berkeley Heights, NJ 07922

Made in Switzerland

**NEW  
FORMULATION**Rev. March 2025  
BH130USTZV350

Outlet port



NDC 0143-9467-01

Rx Only

TYZAVAN  
(vancomycin injection, USP)  
1.75 g/350 mL (5 mg/mL)Single-Dose Flexible Bag  
Sterile, NonpyrogenicNEW FORMULATION  
Ready To Use

Dosage: See Prescribing Information.  
For Intravenous Infusion Only  
Infuse over at least 60 minutes.

1.75 g

Cautions:

Do not add supplementary medication  
or additives. Discard unused portion.

Store at 15°C to 25°C (59°F to 77°F), in original package.  
Use within 28 days of removal from aluminum overpouch.

Each 100 mL contains: Vancomycin hydrochloride equivalent  
to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and  
1.26 g L-lysine hydrochloride in water for injection.  
pH may have been adjusted with hydrochloric acid  
and/or sodium hydroxide.

Manufactured for Hikma Pharmaceuticals USA, Inc.  
Berkeley Heights, NJ 07922

Made in Switzerland  
Rev. March 2025

Hikma

0130USTZV350

NDC 0143-9467-01

Rx Only

**TYZAVAN<sup>®</sup>**

(vancomycin injection, USP)

**1.75 g/350 mL (5 mg/mL)**

Single-Dose Flexible Bag

Sterile, Nonpyrogenic

**NEW FORMULATION**

Ready To Use

Dosage: See Prescribing Information.

For Intravenous Infusion Only

Infuse over at least 60 minutes.

**1.75 g**

**Cautions:**

Do not add supplementary medication or additives. Discard unused portion.

Store at 15°C to 25°C (59°F to 77°F), in original package. Use within 28 days of removal from aluminum overpouch.

Each 100 mL contains: Vancomycin hydrochloride equivalent to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride in water for injection. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.



Manufactured for Hikma Pharmaceuticals USA, Inc.  
Berkeley Heights, NJ 07922  
Made in Switzerland  
Rev. March 2025



**hikma.**

0130USTZV350

LOT: XXXXXXXX

EXP.: YYY MMM

**1.75 g/350 mL**  
(5 mg/mL)

**TYZAVAN<sup>®</sup>**  
(vancomycin injection, USP)

Rx Only  
Sterile

NDC 0143-9467-06  
Contains six (6) single-dose  
Flexible Bags of NDC 0143-9467-01

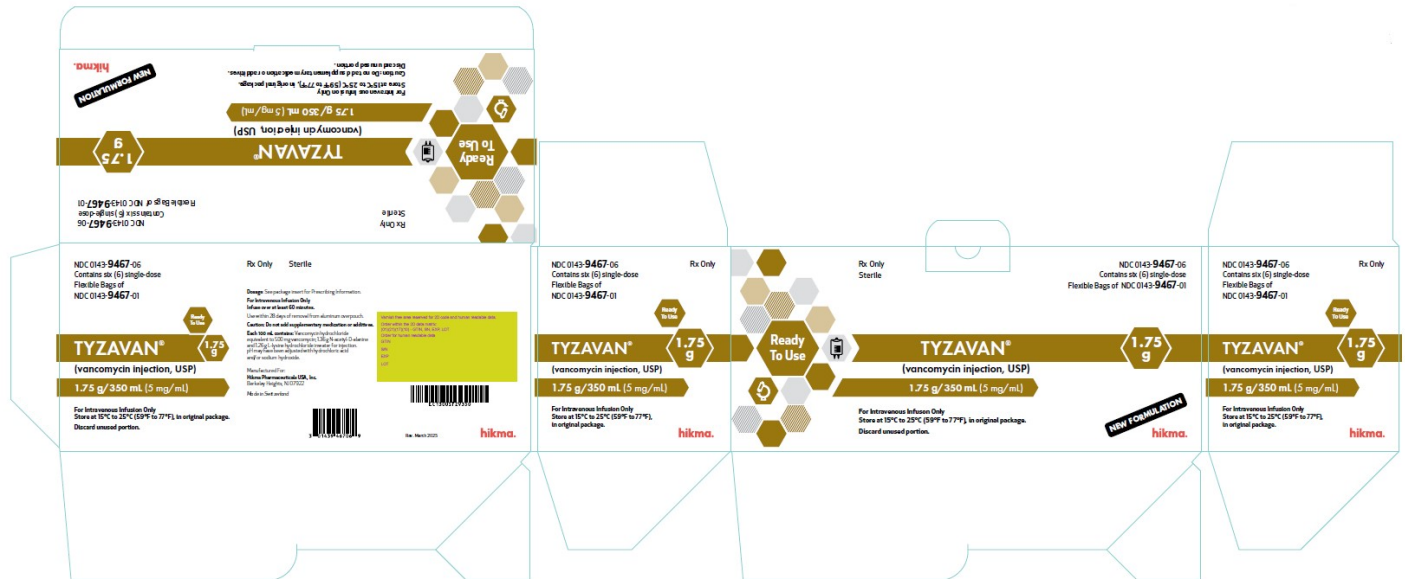
Ready  
To Use

TYZAVAN  
(vancomycin injection, USP)  
1.75 g/350 mL (5 mg/mL)

For Intravenous Infusion Only  
Store at 15°F to 25°C (59°F to 77°F), in original package.  
Discard unused portion.

1.75 g

## NEW FORMULATION



## PRINCIPAL DISPLAY PANEL - 2 g/400mL

NDC 0143-9470-01

LOT

EXP

Rx Only

NEW

FORMULATION

TYZAVAN

(vancomycin injection, USP)

2 g/400 mL (5 mg/mL)

Single-Dose Flexible Bag

Sterile, Nonpyrogenic

Dosage: See Prescribing Information.

For Intravenous Infusion Only

Infuse over at least 60 minutes.

Cautions: Do not add supplementary medication or additives. Discard unused portion.

Store at 15°C to 25°C (59°F to 77°F), in original package.

Use within 28 days of removal from aluminum overpouch.

Each 100 mL contains: Vancomycin hydrochloride equivalent to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride in water for injection.

pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Manufactured for Hikma Pharmaceuticals USA, Inc.

Berkeley Heights, NJ 07922

2 g

Ready  
To Use

NEW  
FORMULATION

Made in Switzerland  
BH130USTZV400

Rev. March 2025

Outlet port

XXXXXXXX

YYYY MMM

LOT

EXP

NDC 0143-9470-01

Rx Only

**NEW  
FORMULATION**

**TYZAVAN<sup>®</sup>**  
 (vancomycin injection, USP)  
 2 g/400 mL (5 mg/mL)

Single-Dose Flexible Bag

Sterile, Nonpyrogenic

**Dosage:** See Prescribing Information.  
**For Intravenous Infusion Only**  
 Infuse over at least 60 minutes.

**2 g**

**Cautions:** Do not add supplementary medication or additives. Discard unused portion.

**Ready  
To Use**

**Store at 15°C to 25°C (59°F to 77°F), in original package.**  
 Use within 28 days of removal from aluminum overpouch.

**Each 100 mL contains:** Vancomycin hydrochloride equivalent to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride in water for injection. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Manufactured for **Hikma Pharmaceuticals USA, Inc.**  
 Berkeley Heights, NJ 07922

**NEW  
FORMULATION**

Made in Switzerland

  
 (01)00301439470014

Rev. March 2025  
 BH130USTZV400



Outlet port



NDC 0143-9470-01

Rx Only

TYZAVAN  
 (vancomycin injection, USP)  
 2 g/400 mL (5 mg/mL)

Single-Dose Flexible Bag  
 Sterile, Nonpyrogenic

NEW FORMULATION  
 Ready To Use

Dosage: See Prescribing Information.  
For Intravenous Infusion Only  
Infuse over at least 60 minutes.

2 g

Cautions:

Do not add supplementary medication  
or additives. Discard unused portion.

Store at 15°C to 25°C (59°F to 77°F), in original package.  
Use within 28 days of removal from aluminum overpouch.

Each 100 mL contains: Vancomycin hydrochloride equivalent  
to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and  
1.26 g L-lysine hydrochloride in water for injection.  
pH may have been adjusted with hydrochloric acid  
and/or sodium hydroxide.

Manufactured for Hikma Pharmaceuticals USA, Inc.  
Berkeley Heights, NJ 07922

Made in Switzerland  
Rev. March 2025

Hikma

0130USTZV400

NDC 0143-9470-01

Rx Only

**TYZAVAN<sup>®</sup>**

(vancomycin injection, USP)

**2 g/400 mL (5 mg/mL)**

Single-Dose Flexible Bag

Sterile, Nonpyrogenic

**NEW FORMULATION**

Ready To Use

**Dosage:** See Prescribing Information.  
**For Intravenous Infusion Only**  
**Infuse over at least 60 minutes.**

**2g**

**Cautions:**

Do not add supplementary medication or additives. Discard unused portion.

**Store at 15°C to 25°C (59°F to 77°F), in original package.**  
Use within 28 days of removal from aluminum overpouch.

**Each 100 mL contains:** Vancomycin hydrochloride equivalent to 500 mg vancomycin; 1.36 g N-acetyl-D-alanine and 1.26 g L-lysine hydrochloride in water for injection. pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.



Manufactured for **Hikma Pharmaceuticals USA, Inc.**  
Berkeley Heights, NJ 07922  
Made in Switzerland  
Rev. March 2025



**hikma.**

0130USTZV400

LOT: XXXXXXXX

EXP.: WYY MMM

**2 g/400 mL**  
(5 mg/mL)

**TYZAVAN<sup>®</sup>**  
(vancomycin injection, USP)

Rx Only  
Sterile

NDC 0143-9470-06  
Contains six (6) single-dose  
Flexible Bags of NDC 0143-9470-01

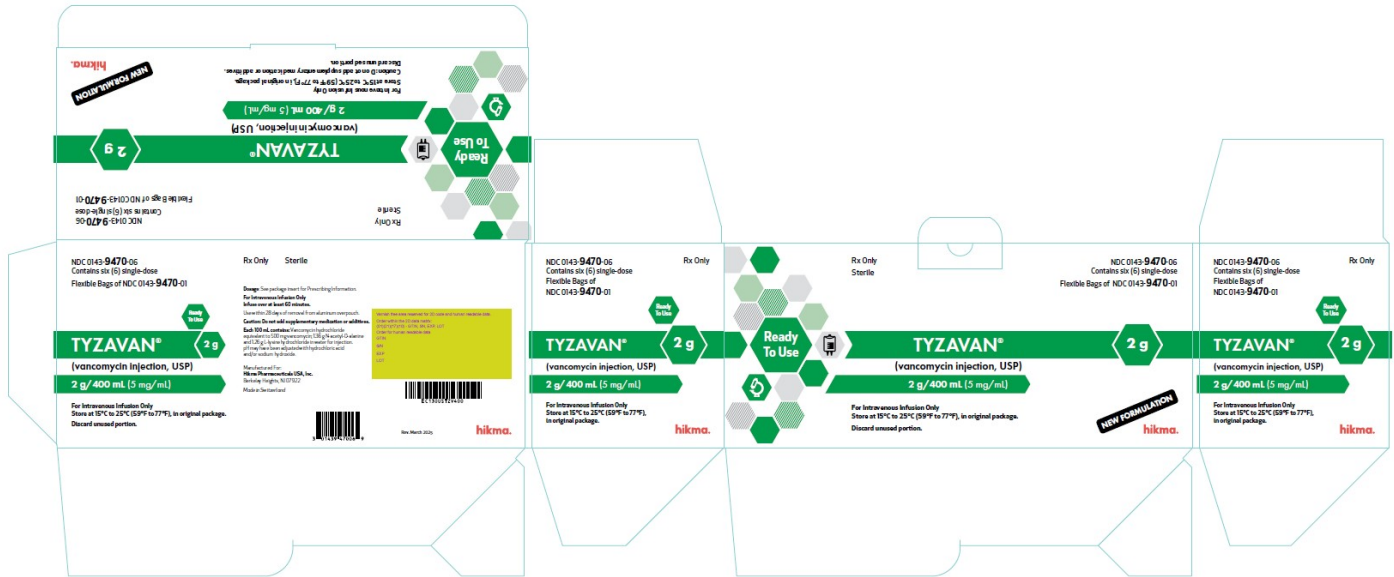
Ready  
To Use

TYZAVAN  
(vancomycin injection, USP)  
2 g/400 mL (5 mg/mL)

For Intravenous Infusion Only  
Store at 15°F to 25°C (59°F to 77°F), in original package.  
Discard unused portion.

2 g

NEW FORMULATION



**TYZAVAN**

vancomycin injection, solution

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0143-9471
<b>Route of Administration</b>	INTRAVENOUS		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
N-ACETYL-D-ALANINE (UNII: IIE41SBQ9L)	
LYSINE HYDROCHLORIDE (UNII: JNJ23Q2COM)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0143-9471-06	6 in 1 CARTON	10/17/2025	

1	NDC:0143-9471-01	100 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0143-9471-12	12 in 1 CARTON	10/17/2025	
2	NDC:0143-9471-01	100 mL in 1 BAG; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA211962	10/17/2025	

## TYZAVAN

vancomycin injection, solution

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0143-9472
Route of Administration	INTRAVENOUS		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
N-ACETYL-D-ALANINE (UNII: IIE41SBQ9L)	
LYSINE HYDROCHLORIDE (UNII: JNJ23Q2COM)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0143-9472-06	6 in 1 CARTON	10/17/2025	
1	NDC:0143-9472-01	200 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0143-9472-12	12 in 1 CARTON	10/17/2025	
2	NDC:0143-9472-01	200 mL in 1 BAG; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA211962	10/17/2025	

## TYZAVAN

vancomycin injection, solution

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0143-9469
Route of Administration	INTRAVENOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VANCOMYCIN (UNII: 6Q205EH1VU) (VANCOMYCIN - UNII:6Q205EH1VU)	VANCOMYCIN	1.5 g in 300 mL

### Inactive Ingredients

Ingredient Name	Strength
N-ACETYL-D-ALANINE (UNII: IIE41SBQ9L)	
LYSINE HYDROCHLORIDE (UNII: JNJ23Q2COM)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0143-9469-06	6 in 1 CARTON	10/17/2025	
1	NDC:0143-9469-01	300 mL in 1 BAG; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA211962	10/17/2025	

## TYZAVAN

vancomycin injection, solution

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0143-9470
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**Route of Administration** INTRAVENOUS

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VANCOMYCIN (UNII: 6Q205EH1VU) (VANCOMYCIN - UNII:6Q205EH1VU)	VANCOMYCIN	2 g in 400 mL

### Inactive Ingredients

Ingredient Name	Strength
N-ACETYL-D-ALANINE (UNII: IIE41SBQ9L)	
LYSINE HYDROCHLORIDE (UNII: JNJ23Q2COM)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0143-9470-06	6 in 1 CARTON	10/17/2025	
1	NDC:0143-9470-01	400 mL in 1 BAG; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA211962	10/17/2025	

## TYZAVAN

vancomycin injection, solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0143-9468
<b>Route of Administration</b>	INTRAVENOUS		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
N-ACETYL-D-ALANINE (UNII: IIE41SBQ9L)	

**LYSINE HYDROCHLORIDE** (UNII: JNJ23Q2COM)

**HYDROCHLORIC ACID** (UNII: QTT17582CB)

**SODIUM HYDROXIDE** (UNII: 55X04QC32I)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0143-9468-06	6 in 1 CARTON	10/17/2025	
1	NDC:0143-9468-01	150 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0143-9468-12	12 in 1 CARTON	10/17/2025	
2	NDC:0143-9468-01	150 mL in 1 BAG; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA211962	10/17/2025	

## TYZAVAN

vancomycin injection, solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0143-9466
<b>Route of Administration</b>	INTRAVENOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>VANCOMYCIN</b> (UNII: 6Q205EH1VU) (VANCOMYCIN - UNII:6Q205EH1VU)	VANCOMYCIN	1.25 g in 250 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>N-ACETYL-D-ALANINE</b> (UNII: IIE41SBQ9L)	
<b>LYSINE HYDROCHLORIDE</b> (UNII: JNJ23Q2COM)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:0143-9466-06	6 in 1 CARTON	10/17/2025	
1	NDC:0143-9466-01	250 mL in 1 BAG; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA211962	10/17/2025	

## TYZAVAN

vancomycin injection, solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0143-9467
<b>Route of Administration</b>	INTRAVENOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VANCOMYCIN (UNII: 6Q205EH1VU) (VANCOMYCIN - UNII:6Q205EH1VU)	VANCOMYCIN	1.75 g in 350 mL

### Inactive Ingredients

Ingredient Name	Strength
N-ACETYL-D-ALANINE (UNII: IIE41SBQ9L)	
LYSINE HYDROCHLORIDE (UNII: JNJ23Q2COM)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0143-9467-06	6 in 1 CARTON	10/17/2025	
1	NDC:0143-9467-01	350 mL in 1 BAG; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA211962	10/17/2025	

Revised: 10/2025

Hikma Pharmaceuticals USA Inc.