TYZAVAN™
(vancomycin injection, USP)

Implementation Guide for Current Users

A practical guide to support systemwide transition to TYZAVAN™

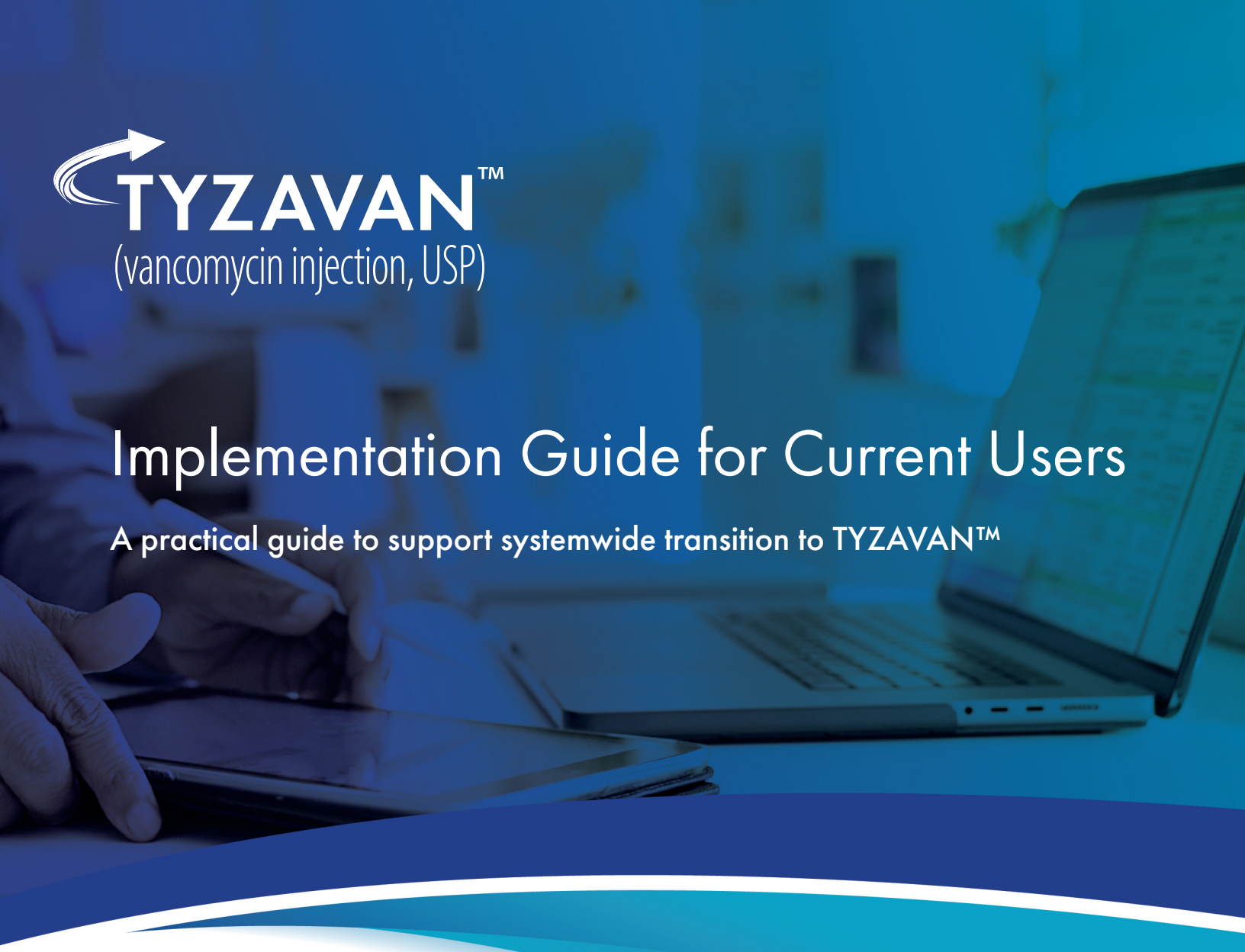


TABLE OF CONTENTS

IMPORTANT SAFETY INFORMATION FOR TYZAVAN™ (vancomycin injection, USP):

CONTRAINDICATIONS

TYZAVAN™ is contraindicated in patients with known hypersensitivity to vancomycin.

WARNINGS & PRECAUTIONS

- **Infusion Reactions –** Hypotension, including shock and cardiac arrest, wheezing, dyspnea, urticaria or pruritus, muscular and chest pain and "vancomycin infusion reactions" which manifests as pruritus and erythema face, neck and upper body pruritus and erythema may occur with rapid TYZAVAN™ administration (e.g., over several minutes). The reactions may be more severe in pediatric patients. To reduce the risk of infusion reactions, administer TYZAVAN™ over a period of 60 minutes or greater and also prior to intravenous anesthetic agents.

Please see full Important Safety Information on pages 27–28 and full Prescribing Information.

Table of Contents

TYZAVAN™ (vancomycin injection, USP)

Overview 3

Introducing TYZAVAN™ 4

Whats New For TYZAVAN™ 5-8

Updates To Prescribing Information 5

Updates To Package Label: Primary Container Bag 6

Updates To Package Label: Overpouch 7

Updates To Package Label: Carton Front Panel 8

Transition Timeline 9

Transition Milestones 10-13

Transition Milestones: Preparation Checklist 11

Transition Milestones: Go-Live Checklist 12

Transition Milestones: Post-Launch Checklist 13

Best Practices For EHR Updates 14

Supply & Dispensing 15

TYZAVAN™ Product Codes 16

Administration 17

Billing 18

How To Order TYZAVAN™ 19

Training & Communication 20

Frequently Asked Questions 21-25

FAQ: Product Information 21

FAQ: Supply Management 22

FAQ: Ordering & Codes 23

FAQ: Systems & Operations 24

FAQ: Training & Communication 25

Contact Us & References 26

Important Safety Information 27-28

TYZAVAN™ (vancomycin injection, USP)

Overview

With the launch of TYZAVAN™ and discontinuation of the original formulation, hospitals should begin to update EHR and supporting systems. This guide provides practical guidance to support a smooth transition to TYZAVAN™ with minimal disruption, including:

- Updating EHRs, ADCs, and smart-pump libraries
- Mapping orderables, barcodes, and NDCs to ensure accurate dispensing and billing
- Training pharmacy, nursing, and other staff on the updated product and workflows
- Managing dual inventory of TYZAVAN™ and Vancomycin Injection, USP* during transition

*Vancomycin Injection, USP was manufactured for Xellia Pharmaceuticals USA, LLC, distributed by Hikma, and referred to as VancoReady. A "Dear HCP" letter was sent to the HCP community to discuss the issue of both products simultaneously being on the market.

ADC, Automatic Dispensing Cabinet; EHR, Electronic Health Record; NDC, National Drug Code.

TYZAVAN™ (vancomycin injection, USP)

Introducing TYZAVAN™ (vancomycin injection, USP)

In June 2025, the FDA approved a reformulation of Hikma's ready-to-use, room-temperature stable premix Vancomycin Injection, USP approved to be marketed under the brand name TYZAVAN™.[1] TYZAVAN™ will fully replace the original formulation previously marketed as VancoReady, which is being discontinued and phased out.[1]

Unchanged in What Matters Most

TYZAVAN™ comes with the same indications, strengths, concentration, and volumes as the original formulation. It also retains many of the same trusted product attributes:

READY-TO-USE[2]

No thawing, compounding, or diluting. Just administer

AVAILABLE IN 7 STRENGTHS[2]

500 mg, 750 mg, 1 g, 1.25 g, 1.5 g, 1.75 g, 2 g

ROOM-TEMPERATURE STABLE[2]

15 °C to 25 °C (59 °F to 77 °F)

cGMP-MANUFACTURED

Manufactured to the highest quality standards and USP <797>-compliant

16-MONTH SHELF LIFE[1,*]

in aluminum overpouch

CODE-CART AND ADC-COMPATIBLE

Designed to support simple dispensing at the point of care

*Use within 28 days of removal from the aluminum overpouch.

ADC, Automatic Dispensing Cabinet.

Please see full Important Safety Information on pages 27–28 and full Prescribing Information.

What's New for TYZAVAN™

The key difference between TYZAVAN™ and the original formulation is that TYZAVAN™ is not subject to the Boxed Warning associated with the original formulation.[1,3] TYZAVAN™ will be introduced as a Hikma-branded product with new NDCs.[1] Changes were also made to the packaging.

Updates to Prescribing Information[1,2]

- Boxed Warning was removed
- The warning "Potential Risk of Exposure to Excipients During the First or Second Trimester of Pregnancy" was removed from:
  - WARNING AND PRECAUTIONS (SECTION 5)
  - PATIENT COUNSELING INFORMATION (SECTION 17)
- The recommendation to obtain a pregnancy test in females of reproductive potential was removed from:
  - DOSAGE AND ADMINISTRATION (SECTION 2)
  - USE IN SPECIFIC POPULATIONS (SECTION 8)

TYZAVAN™ (vancomycin injection, USP)

What's New for TYZAVAN™ (cont.)

Updates to Package Label

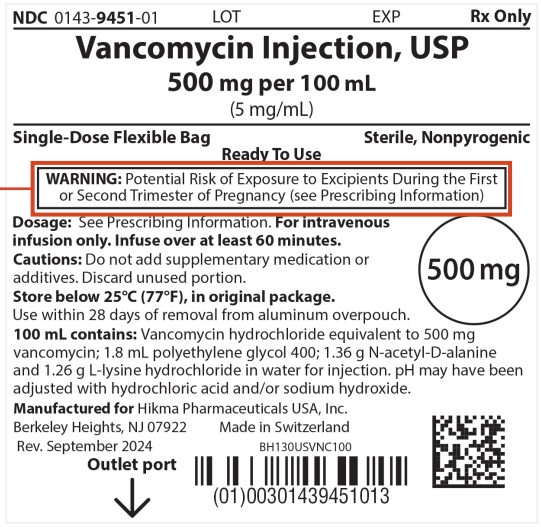
TYZAVAN™ packaging will be similar to that of the original formulation with the same color-coding per strength and the following updates highlighted below.

Examples show labeling for Vancomycin Injection, USP 500 mg and TYZAVAN™ 500 mg.

PRIMARY CONTAINER BAG

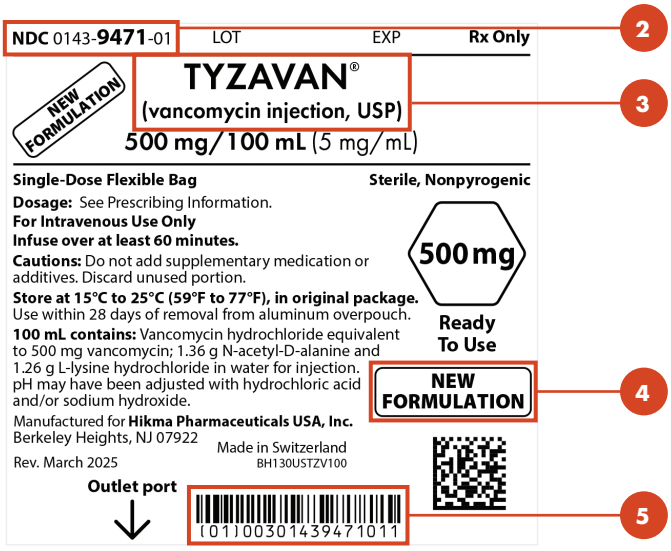
OLD LABEL

Vancomycin Injection, USP 500 mg



NEW TYZAVAN™ LABEL

TYZAVAN™ 500 mg



Label Updates

1. TYZAVAN™ has no Boxed Warning
2. New NDC
3. TYZAVAN™ brand name added
4. "New Formulation" label
5. New barcode

TYZAVAN™ (vancomycin injection, USP)

What's New for TYZAVAN™ (cont.)

Updates to Package Label (cont.)

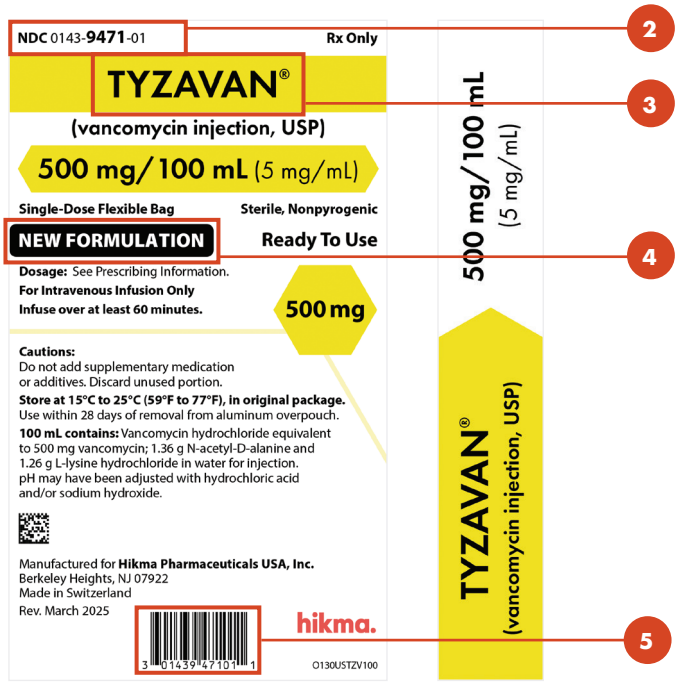
OVERPOUCH

OLD LABEL

Vancomycin Injection, USP 500 mg

NEW TYZAVAN™ LABEL

TYZAVAN™ 500 mg



Label Updates

1. TYZAVAN™ has no Boxed Warning
2. New NDC
3. TYZAVAN™ brand name added
4. "New Formulation" label
5. New barcode

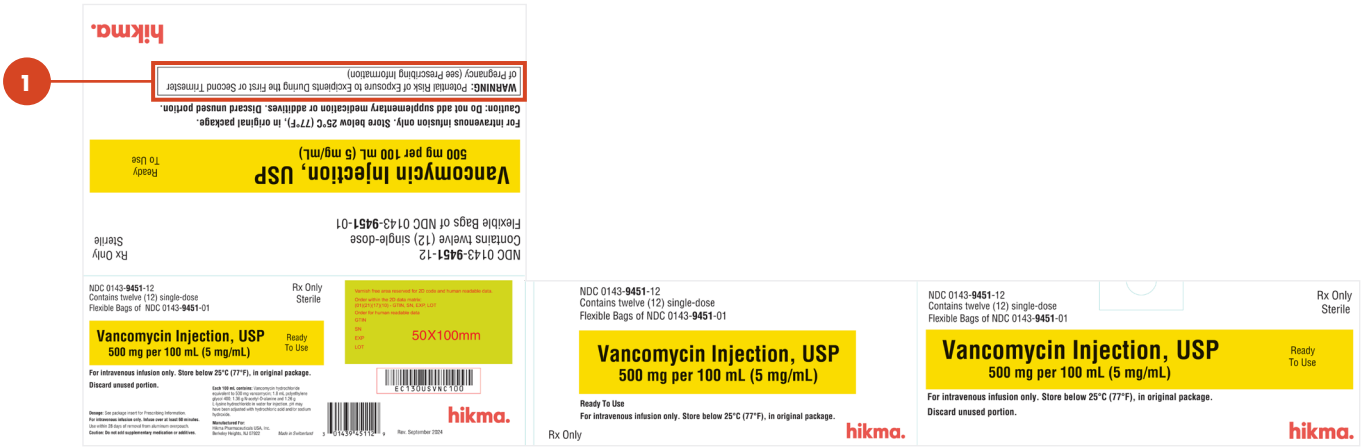
What's New for TYZAVAN™ (cont.)

Updates to Package Label (cont.)

CARTON FRONT PANEL

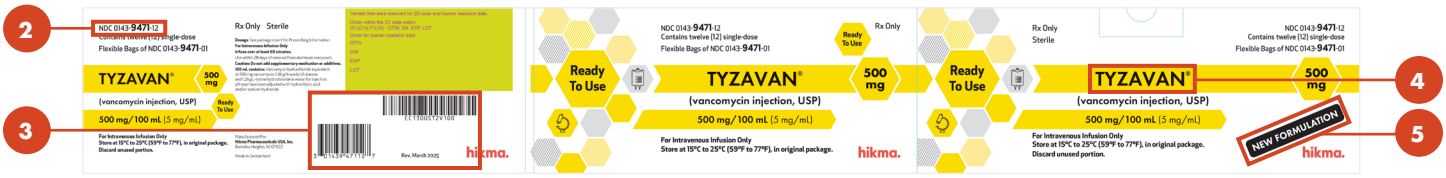
OLD LABEL

Vancomycin Injection, USP 500 mg



NEW TYZAVAN™ LABEL

TYZAVAN™ 500 mg



Label Updates

1. TYZAVAN™ has no Boxed Warning
2. New NDC
3. New barcodes
4. TYZAVAN™ brand name added
5. "New Formulation" label

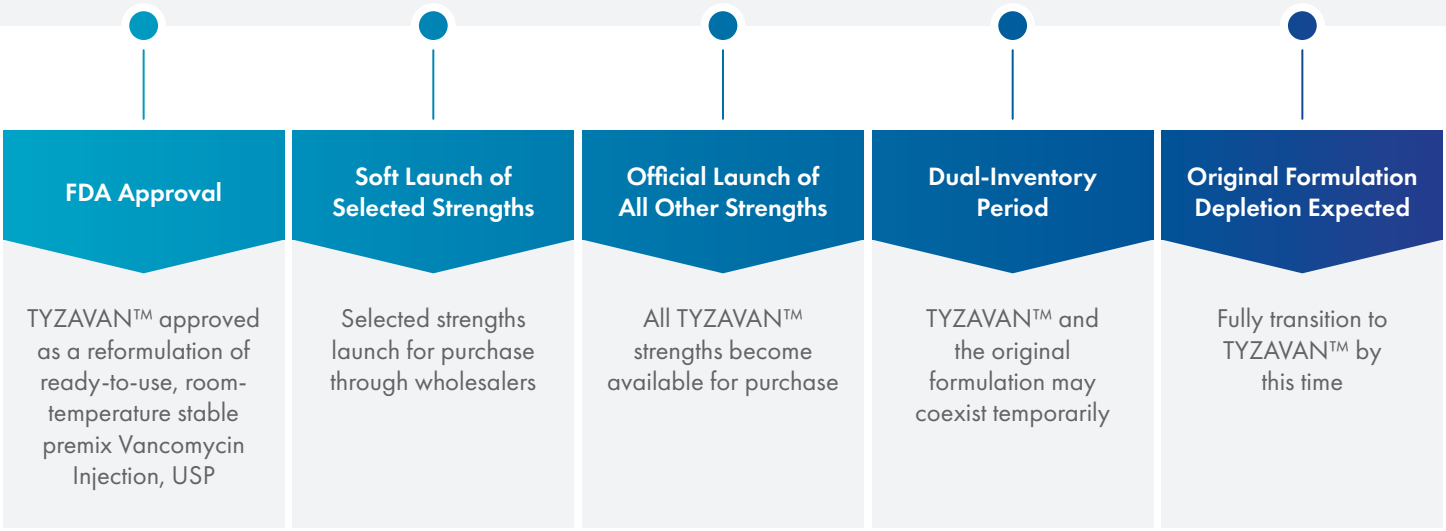
TYZAVAN™ (vancomycin injection, USP)

Transition Timeline

TYZAVAN™ will fully replace the original formulation. TYZAVAN™ is being released in phases, with all strengths expected to be available by early December 2025. Ask your Hikma representative about the availability of specific strengths. Existing inventory of the original formulation is expected to run out by H2-2026, although specific strengths will run out earlier.

To ensure uninterrupted access, start preparing to transition to TYZAVAN™ at least one month prior to your hospital's planned go-live date. Early coordination among pharmacy, IT, and nursing teams prior to the go-live date will help prevent workflow disruptions and support continuity of patient care.

Key Transition Dates



TYZAVAN™ (vancomycin injection, USP)

Transition Milestones

01 PREPARATION

4–6 weeks prior to go-live

Update systems (including EHR), order TYZAVAN™, and announce the transition

PHASE 1 CHECKLIST

02 GO-LIVE

At launch

Introduce TYZAVAN™ across hospital systems and confirm that all systems are up-to-date

PHASE 2 CHECKLIST

03 POST-LAUNCH

First 1–3 months

Report any issues to Hikma, and complete transition once the original formulation is depleted

PHASE 3 CHECKLIST

REMINDER: Track original formulation stock for each strength and order TYZAVAN™ equivalents as needed.

EHR, Electronic Health Record.

Transition Milestones (cont.)

01 PREPARATION CHECKLIST

At least 4 weeks prior to go-live date

PLAN

- Align on go-live timing and set dual-inventory plans with pharmacy, nursing, procurement, and IT
- Plan and place orders for TYZAVAN™

UPDATE EHR

- Integrate NDCs, barcodes, and order sets for TYZAVAN™ into EHR
- Add TYZAVAN™ to drug databases, and billing systems

EHR BEST PRACTICES

SYNC SYSTEMS

- Adjust infusion protocols and dosing calculators as needed
- Ensure dose libraries, concentrations, and infusion parameters match original formulation equivalents

ANNOUNCE

- Share timeline and transition details with staff via announcements and huddles
- Define process for managing dual inventories during transition
- Identify a cutoff date for the original formulation

ALIGN

- Replicate updates across each facility in multi-site health systems if order sets are not shared

BACK

EHR, Electronic Health Record; NDC, National Drug Code.

Transition Milestones (cont.)

02 GO-LIVE CHECKLIST

At launch

SWAP

- Add TYZAVAN™ to ADCs and central pharmacy storage

TEST

- Verify EHR functionality again prior to go-live date
- Test orders and barcode scans to ensure proper mapping and dispensing

REMIND

- Notify staff on launch day
- Install alerts and in-system messages to confirm the switch is active

BACK

ADC, Automatic Dispensing Cabinet; EHR, Electronic Health Record.

Transition Milestones (cont.)

03 POST-LAUNCH CHECKLIST

First 1–3 months

MONITOR

- Validate that all systems properly populate TYZAVAN™ and orders link to ADC and smart pumps

MAINTAIN

- Honor existing original formulation orders only until inventory is depleted
- Keep both TYZAVAN™ and original formulation records while both are available

REFINE

- Document and report issues to Hikma
- Capture workflow or system feedback for process improvement

DELETE

- Once the original formulation is depleted, remove all related orderables and references from EHR and ADC systems

BACK

ADC, Automatic Dispensing Cabinet; EHR, Electronic Health Record.

Best Practices for EHR Updates

Transitioning from the original formulation to TYZAVAN™ requires coordinated updates across pharmacy systems, EHR configuration, and hospital operations. Depending on the EHR system setup, this may involve substituting existing EHR records or creating new ones.

Creating a New EHR Record

Parallel Record Management
- Keep the original formulation and TYZAVAN™ active until transition completion
- Define the original formulation phase-out date in appropriate systems

Databank Integration
- Confirm TYZAVAN™ is in primary drug databases and queued for next databank release

Default Ordering
- Configure rules to substitute TYZAVAN™ automatically when the original formulation runs out

Clinical Decision Support
- Rebuild alerts, dosing guidance, and infusion parameters to reference TYZAVAN™

Formulary Alignment
- Verify TYZAVAN™ is correctly flagged in formulary management systems

Substitution of the original formulation

Record Updates
- Replace the original formulation fields with TYZAVAN™ identifiers where appropriate

Boxed Warning Alert Removal
- Remove or reconfigure automated alerts, pop-ups, or warnings related to Boxed Warning
- Confirm that rules do not require pregnancy screening or restrictive warnings for TYZAVAN™

System Synchronization
- Confirm substitutions sync across ADCs, pumps, and billing

ADC, Automatic Dispensing Cabinet; EHR, Electronic Health Record.

Supply & Dispensing

Dual Inventory Management

Both the original formulation and TYZAVAN™ may need to remain listed and stocked during the transition period, until the original formulation inventory is depleted. Clear labeling of shelves and bins, and the configuration of alerts to distinguish between the two products can prevent selection errors. A "Dear HCP" letter was sent to the HCP community to discuss the issue of both products simultaneously being on the market.

Automatic Dispensing Cabinets (ADCs)

TYZAVAN™ bag and carton dimensions remain the same as the original formulation. ADC systems must be updated with TYZAVAN™ as a new product entry with unique NDCs.

1. Add TYZAVAN™ Entries

- Create new ADC entries using TYZAVAN™ NDCs
- Map to the EHR and pharmacy systems to align barcodes and identifiers
- Verify labeling, bin assignments, and barcode scanning for all stocked strengths

2. Remove the Original Formulation

- Delete original formulation (it could possibly be labeled VancoReady) entries once inventory is depleted
- Remove any linked alerts, dose limits, or warnings

3. Verify Integration

- Confirm ADC data syncs with the pharmacy information system and EHR
- Check that inventory counts, reorder points, and billing pathways link to TYZAVAN™

ADC, Automatic Dispensing Cabinet; EHR, Electronic Health Record; NDC, National Drug Code.

TYZAVAN™ (vancomycin injection, USP)

TYZAVAN™ Product Codes

Total Unit Content	Label Color	Unit of Sale NDC	Total Premix Bag Volume	Pack Size (Bag Per Case)	Bag Barcode	Carton Barcode
2 g		0143-9470-06	400 mL	6	(01)00301439470014	3 01439 47006 9
1.75 g		0143-9467-06	350 mL	6	(01)00301439467014	3 01439 46706 9
1.5 g		0143-9469-06	300 mL	6	(01)00301439469018	3 01439 46906 3
1.25 g		0143-9466-06	250 mL	6	(01)00301439466017	3 01439 46606 2
1 g		0143-9472-12	200 mL	12	(01)00301439472018	3 01439 47212 4
750 mg		0143-9468-12	150 mL	12	(01)00301439468011	3 01439 46812 7
500 mg		0143-9471-12	100 mL	12	(01)00301439471011	3 01439 47112 7

TYZAVAN™ bag and carton dimensions remain the same as the original formulation.

Administration

TYZAVAN™ maintains the same concentration, dosing, and infusion parameters as the original formulation. Therefore, administration steps and procedures do not require change.

Infusion Pump Settings

Most hospitals will not need to modify existing pump configurations. If your hospital uses a smart pump drug library, verify that TYZAVAN™ has been added and ensure that safety alerts, dose limits, and warnings linked to the original formulation do not apply to TYZAVAN™.

Pump and IV Set Compatibility

TYZAVAN™ is designed for seamless integration with standard IV administration sets and infusion pumps used across US hospitals.

In-house compatibility studies confirmed secure spike connections, consistent flow, and full functional compatibility with most commonly used devices.

The same IV sets, tubing, and port design that are compatible with Vancomycin Injection, USP (original formulation) will also be compatible with TYZAVAN™ (reformulation).

TIP: Before go-live, connect a TYZAVAN™ premix bag to an IV set and pump system that you intend to use to confirm proper fit and flow.

CONTACT YOUR HIKMA REPRESENTATIVE FOR SUPPORT IF NEEDED.

Billing

TYZAVAN™ products carry both new national drug codes (NDCs) and must be billed under these codes. Because TYZAVAN™ is a reformulated product, it cannot be billed under previous identifiers.

340B and Pricing Considerations

As a reformulation with new NDCs, TYZAVAN™ cannot be substituted under the existing 340B pricing. Hospitals participating in the 340B Drug Pricing Program will need to initially purchase TYZAVAN™ at its Wholesale Acquisition Cost (WAC) to re-establish 340B eligibility.

J-Code for Claims Submission

TYZAVAN™ has the same J-code as the original formulation (Vancomycin Injection, USP). When submitting claims for TYZAVAN™, use the specific J-code designated for this product.

J-Code	Description	Effective Date
J3375	Injection, vancomycin hydrochloride, not therapeutically equivalent to J3373, 10 mg*	November 14, 2025

Ensure that your billing, EHR, and charge master systems are updated with the correct:

- J-code for TYZAVAN™
- NDCs for each strength
- Package description

*Updated on November 14, 2025, to remove the establishment of HCPCS Level II code J3377, "Injection, vancomycin hcl (TYZAVAN™), 10 mg" as the product falls under the same NDA as all the original formulation's (Vancomycin Injection, USP) National Drug Codes listed under HCPCS Level II code J3375.

EHR, Electronic Health Record; NDC, National Drug Code; WAC, Wholesale Acquisition Cost.

TYZAVAN™ (vancomycin injection, USP)

How to Order TYZAVAN™

TYZAVAN™ can be purchased through major distributors, including Cencora, Cardinal, McKesson, and Morris & Dickson. A Hikma sales representative can also assist with placing orders. Contact your representative or email us at **usinjcommercialmarketing@hikma.com** for additional support.

For orders placed through major distributors, there is no automatic substitution between the original formulation and TYZAVAN™, and new orders will need to be placed.

Pricing

GPO pricing for all TYZAVAN™ products will remain the same as the original formulation.

Product Information

Total Unit Content	2 g	1.75 g	1.5 g	1.25 g	1 g	750 mg	500 mg
Label Color							
Unit of Sale NDC	0143-9470-06	0143-9467-06	0143-9469-06	0143-9466-06	0143-9472-12	0143-9468-12	0143-9471-12
Total Premix Bag Volume	400 mL	350 mL	300 mL	250 mL	200 mL	150 mL	100 mL
Pack Size (Bag Per Case)	6	6	6	6	12	12	12

Training & Communication

Since TYZAVAN™ has the same identical strengths, concentration, and administration as the original formulation, minimal staff training is needed.[2,3]

Clear hospital-wide communications before, during, and after the go-live date remains important to inform staff about the transition to TYZAVAN™ and rationale, how it impacts their work, and key dates and milestones.

Staff education should focus on the formulation change, new labeling, and updated NDCs to promote accurate identification and billing and proper use. Appropriate hospital employees will also receive the "Dear HCP" letter in support of the transition.

Universal Communications

- **Communicate phase-in timeline**
- **Educate staff about TYZAVAN™** – Highlight updates to the Prescribing Information (see **What's New for TYZAVAN™** section)
- **Send announcements before, during, and after go-live date** – Announce the switch to TYZAVAN™ and rationale. Consider electronic newsletters, team huddles, or system alerts, especially during the first few weeks post-launch
- **Pregnancy screening protocols** – Align with institutional policy while both formulations remain in stock

For Clinical and Nursing Teams:

- Advise that administration process and workflow remain the same
- Inform nurses about labeling updates and product appearance (see **What's New for TYZAVAN™** section)

For Pharmacy Teams:

- Inform staff about new TYZAVAN™ NDCs
- Advise staff to:
  - Validate barcode scanning before use to ensure accurate mapping
  - Label ADC bins and shelves clearly during dual-inventory phase

ADC, Automatic Dispensing Cabinet; NDC, National Drug Code.

Frequently Asked Questions

Product Information

Q1. What is TYZAVAN™ and who can use it?

A1. 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[2]:

- Septicemia
- Infective Endocarditis
- Skin and Skin Structure Infections
- Bone Infections
- Lower Respiratory Tract Infections

See the **Prescribing Information** for the full indication.

Q2. Are there changes to the package insert from the original formulation?

A2. Yes, the FDA approved TYZAVAN™ with no Boxed Warning.[2,3]

In the Prescribing Information, the warning "Potential Risk of Exposure to Excipients During the First or Second Trimester of Pregnancy" subsections was removed from the WARNING AND PRECAUTIONS (SECTION 5); and PATIENT COUNSELING INFORMATION (SECTION 17) sections along with the approval of the formulation change.[2,3]

Finally, the recommendation to obtain a pregnancy test in females of reproductive potential was removed from both the DOSAGE AND ADMINISTRATION (SECTION 2) and USE IN SPECIFIC POPULATIONS (SECTION 8) sections.[2,3]

Q3. Are there any changes to shelf life or storage conditions?

A3. No, TYZAVAN™ has a 16-month shelf life.[1] It should be stored at room temperature 15 °C to 25 °C (59 °F to 77 °F) in original packaging and must be used within 28 days of removal from the aluminum overpouch.[2]

Q4. Are all the same doses and volumes available?

A4. Yes, all seven strengths will be available in the same concentration (5 mg/mL) and volumes as the original formulation.[2,3]

Q5. What does the new packaging look like?

A5. Packaging will be similar to that of the original formulation with the same color-coding per strength, but marked "New Formulation" and labeled TYZAVAN™. See a **comparison of packaging** between products (pages 6–8).

Frequently Asked Questions (cont.)

Supply Management

Q1. When will various TYZAVAN™ strengths become available?

A1. TYZAVAN™ is being released in phases, starting October 2025, with all strengths expected to be available by early December 2025. For details on the availability of specific strengths, please contact your Hikma representative.

Q2. Will production of the original formulation continue?

A2. No, production has stopped. Existing inventory is shipping, but TYZAVAN™ will eventually replace the original formulation.

Q3. Will there be supply gaps?

A3. Supply disruptions for the original formulation are not expected, but possible. You should discuss a stocking strategy with your Hikma representative to avoid any supply issues. Consider stocking all available strengths of TYZAVAN™ upon launch and/or replenishing the original formulation's inventory while supplies last.

Q4. Will both products exist on the market at the same time?

A4. Yes, during the transition phase, consider carrying both products to ensure there are no gaps in stock.

Q5. How should hospitals handle a mixed inventory?

A5. Clear labeling and communication are recommended. A "Dear HCP" letter was sent to the HCP community to discuss the issue of both products simultaneously being on the market. Do not wait until the original formulation's supplies are depleted to fully transition to TYZAVAN™.

Frequently Asked Questions (cont.)

Ordering & Codes

Q1. Will TYZAVAN™ replace the original formulation automatically through wholesalers?

A1. No. TYZAVAN™ has new NDCs and will be listed as separate items. There will not be automatic substitution in orders, so plan accordingly.

Q2. Which wholesalers will carry TYZAVAN™?

A2. The same major distributors that carry the original formulation will also carry TYZAVAN™.

Q3. Will the J-code change?

A3. No, TYZAVAN™ has the same J-code as the original formulation (Vancomycin Injection, USP): **J3375**

Q4. Will pricing be different?

A4. No, TYZAVAN™ has the same GPO pricing as the original formulation.

GPO, Group Purchasing Organization; NDC, National Drug Code.

Frequently Asked Questions (cont.)

Systems & Operations

Q1. What changes are needed in the EHR?

A1. Hospitals must update NDCs, barcodes, and order sets.

Q2. Are ADCs affected?

A2. Yes, ADCs such as Pyxis™* and Omnicell®† must be updated with the new NDCs.

Q3. Does TYZAVAN™ have special requirements for IV tubing and pumps?

A3. No, TYZAVAN™ is compatible with standard IV tubing, just like the original formulation. Likewise, it is compatible with the same pumps as the original formulation.

Q4. Do pump libraries need to be updated?

A4. Concentration (5 mg/mL) and volumes remain the same for all strengths, so no pump programming changes are likely to be required.[2,3]

*Pyxis™ is a trademark of Becton, Dickinson and Company.

†Omnicell® is a registered trademark of Omnicell, Inc.

ADC, Automatic Dispensing Cabinet; EHR, Electronic Health Record; NDC, National Drug Code.

Frequently Asked Questions (cont.)

Training & Communication

Q1. Will staff training be required?

A1. All staff should be informed about the transition to TYZAVAN™, the key difference being that TYZAVAN™ is not subject to a Boxed Warning and will be introduced as a Hikma-branded product with new NDCs.[1] Staff should also be informed about implications for patient screening and treatment. Nurses should be informed that administration is identical to the original product. Pharmacy staff should be provided with the same information and be updated on NDC and barcode changes.

Q2. Do hospitals need to change pregnancy screening protocols?

A2. TYZAVAN™ was approved without a Boxed Warning, but screening may still be required during the transition period, when both formulations are still available at different doses simultaneously.[1] To ensure patient safety and eliminate confusion, hospitals should align on internal screening policies for the transition period and educate staff.

NDC, National Drug Code.

Contact Us

Contact Hikma's Pharmacovigilance department with any questions about the safe and effective use of TYZAVAN™ (vancomycin injection, USP) and Vancomycin Injection, USP (VancoReady).

PHONE

1-877-845-0689

EMAIL

us.hikma@primevigilance.com

References

1. Hikma Pharmaceuticals. Hikma receives FDA approval for TYZAVAN™ (vancomycin injection, USP) in the US. www.hikma.com/news/hikma-receives-fda-approval-for-tyzavan-vancomycin-injection-usp-in-the-us/. Accessed September 25, 2025.
2. TYZAVAN™ Prescribing Information. Hikma Pharmaceuticals USA Inc.; 2025.
3. Vancomycin Injection, USP Prescribing Information. Hikma Pharmaceuticals USA Inc.; 2025 (marketed as VancoReady)

TYZAVAN™ (vancomycin injection, USP)

Important Safety Information for TYZAVAN™ (vancomycin injection, USP):

CONTRAINDICATIONS

TYZAVAN™ is contraindicated in patients with known hypersensitivity to vancomycin.

WARNINGS & PRECAUTIONS

- **Infusion Reactions –** Hypotension, including shock and cardiac arrest, wheezing, dyspnea, urticaria or pruritus, muscular and chest pain and "vancomycin infusion reactions" which manifests as pruritus and erythema face, neck and upper body pruritus and erythema may occur with rapid TYZAVAN™ administration (e.g., over several minutes). The reactions may be more severe in pediatric patients. To reduce the risk of infusion reactions, administer TYZAVAN™ over a period of 60 minutes or greater and also prior to intravenous anesthetic agents.
- **Nephrotoxicity –** TYZAVAN™ can result in acute kidney injury (AKI), including acute renal failure, mainly due to interstitial nephritis or less commonly acute tubular necrosis. Monitor renal function in all patients.
- **Ototoxicity –** Ototoxicity may be reversible or permanent in patients receiving vancomycin. It is higher risk in older patients and patients who are receiving higher doses and manifests as tinnitus, hearing loss, dizziness or vertigo. Serial tests of auditory function may be helpful.
- **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 TYZAVAN™ at the first appearance of any signs and symptoms of TEN, SJS, DRESS, AGEP, or LABD.
- ***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. Evaluate patients if diarrhea occurs.
- **Hemorrhagic Occlusive Retinal Vasculitis (HORV) –** 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 these routes have not been established by adequate and well-controlled trials. Vancomycin is not indicated for the prophylaxis of endophthalmitis.
- **Neutropenia –** Reversible neutropenia has been reported in patients receiving vancomycin. Periodically monitor leukocyte count.
- **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 to reduce the risk of local irritation and phlebitis. Thrombophlebitis may occur. 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 have not been established by adequate and well controlled trials.
- **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.

ADVERSE REACTIONS

The most common adverse reactions are: (i) anaphylaxis; (ii) "vancomycin infusion reactions"; (iii) acute kidney injury; (iv) hearing loss; and (v) neutropenia.

DRUG INTERACTIONS

Anesthetic Agents: Concomitant administration of vancomycin and anesthetic agents has been associated with erythema and histamine-like flushing.

Please see full Important Safety Information continued on the next page and full Prescribing Information.

Important Safety Information (cont.)

DRUG INTERACTIONS (cont.)

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 functions.

Ototoxic and/or Nephrotoxic Drugs: Concurrent and/or sequential systemic or topical use of other potentially neurotoxic and/or nephrotoxic drugs requires more frequent monitoring of renal function.

USE IN SPECIFIC POPULATIONS

Pregnancy: 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.

Lactation: There are insufficient data to inform the levels of vancomycin in human milk. There are no data on the effects of vancomycin on the breastfed infant or milk production.

Pediatric Use: 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™.

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, and it may be useful to monitor renal function.

Renal Impairment: Dosage adjustment of Vancomycin Injection must be made in patients with impaired renal function. Measure trough vancomycin serum concentrations to guide intravenous therapy, especially in patients with impaired renal function or fluctuating renal function.

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 overdosage, contact the National Poison Control Center at 1-800-222-1222 or www.poison.org.

INDICATIONS AND USAGE

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

- Septicemia
- Infective Endocarditis
- Skin and Skin Structure Infections
- Bone Infections
- Lower Respiratory Tract Infections

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.

For more information about TYZAVAN™, please see the Full Prescribing Information or contact Hikma Pharmaceuticals USA Inc. at us.hikma@primevigilance.com or 1-877-845-0689.

You are encouraged to report negative side effects of prescription drugs to the FDA. To report SUSPECTED ADVERSE REACTIONS, contact Hikma Pharmaceuticals USA Inc. at 1-877-845-0689 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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