

AVAILABLE IN 7 DOSES

FULLY READY FULLY COVERED

VANCO READY[®]

VANCOMYCIN INJECTION, USP

READY TO INFUSE



**The first and only READY TO INFUSE
VANCOMYCIN premix available in 7 DOSES**
Not Frozen • Not Compounded • No Activation

Not to be used during first and second trimester of pregnancy due to excipients.
For full prescribing information, including boxed warning, please visit www.vancoready.com.

xellia
PHARMACEUTICALS

VANCO READY®

VANCOMYCIN INJECTION, USP



READY TO INFUSE

VANCO READY® (Vancomycin Injection, USP)

Total unit content	Label Color	Unit of sale NDC	Total Premix bag Volume	Pack size (bags per case)	Bag barcode	Carton barcode	Wholesaler item number			
							ABC	Cardinal	McKesson	Morris & Dickson
500 mg		70594-041-03	100 mL	12			10231810	5581996	2557577	812529
750 mg		70594-056-03	150 mL	12			10238604	5667456	1563535	907915
1 g		70594-042-03	200 mL	12			10219535	5529037	3945946	605238
1.25 g		70594-057-02	250 mL	6			10238601	5667464	1563543	907931
1.5 g		70594-043-02	300 mL	6			10219893	5529045	3945987	605246
1.75 g		70594-058-02	350 mL	6			10238603	5667472	1563550	907949
2 g		70594-044-02	400 mL	6			10229515	5563838	3979127	777243

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HIGHLIGHTS OF PRESCRIBING INFORMATION

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

VANCOMYCIN injection, for intravenous use
Initial U.S. Approval: 1958

RECENT MAJOR CHANGES

Boxed Warning	10/2021
Warnings and Precautions, Severe Dermatologic Reactions (5.5)	5/2021
Warnings and Precautions, Potential Risk of Exposure to Excipients During the First or Second Trimester of Pregnancy (5.1)	10/2021

WARNING: POTENTIAL RISK OF EXPOSURE TO EXCIPIENTS DURING THE FIRST OR SECOND TRIMESTER OF PREGNANCY

See full prescribing information for complete boxed warning.

If use of vancomycin is needed during the first or second trimester of pregnancy, use other available formulations of vancomycin. This formulation of vancomycin injection contains the excipients polyethylene glycol (PEG 400) and N-acetyl D-alanine (NADA), which resulted in fetal malformations in animal reproduction studies at dose exposures approximately 8 and 32 times, respectively, higher than the exposures at the human equivalent dose (5.1, 8.1).

INDICATIONS AND USAGE

Vancomycin Injection is a glycopeptide antibacterial indicated in adult and pediatric patients (1 month and older) for the treatment of:

- 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 Vancomycin Injection and other antibacterial drugs, Vancomycin Injection should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. (1.6)

DOSAGE AND ADMINISTRATION

- Obtain a pregnancy test in females of reproductive potential prior to initiating treatment with Vancomycin Injection. [see Warnings and Precautions (5.1) and Use in Specific Populations (8.1, 8.3)]
- Use this formulation of Vancomycin Injection only in patients who require the entire (500 mg, 750 mg, 1 g, 1.25 g, 1.5 g, 1.75 g or 2 g) dose and not any fraction thereof. (2.1)
- For intravenous use only. Do **Not** administer orally.
- Administer Vancomycin Injection by intravenous infusion over 60 minutes or greater to reduce the risk of infusion reactions. (2.1)
- **Adult Patients:** 2 g divided either as 0.5 grams (g) every 6 hours or 1 g every 12 hours. (2.2)
- **Pediatric Patients (1 Month and Older):** 10 mg/kg per dose given every 6 hours. (2.3)
- **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 administration and preparation instructions. (2.1, 2.5)

DOSAGE FORMS AND STRENGTHS

Vancomycin Injection, USP: Single-dose flexible bags containing 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 of liquid. (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 "red man syndrome" which manifests as pruritus and erythema that involves the face, neck and upper torso may occur with rapid intravenous administration. To reduce the risk of infusion reactions, administer Vancomycin Injection over a period of 60 minutes or greater and also prior to intravenous anesthetic agents. (2.1, 5.2)
- **Nephrotoxicity:** Systemic vancomycin exposure may result in acute kidney injury (AKI) including acute renal failure, mainly due to interstitial nephritis or less commonly acute tubular necrosis. Monitor serum vancomycin concentrations and renal function. (5.3)
- **Ototoxicity:** Ototoxicity has occurred in patients receiving vancomycin. Monitor for signs and symptoms of ototoxicity during therapy. Monitor serum vancomycin concentrations and renal function. Assessment of auditory function may be appropriate in some instances. (5.4)
- **Severe Dermatologic Reactions:** Discontinue Vancomycin Injection at the first appearance of skin rashes, mucosal lesions, or blisters. (5.5)
- **Clostridioides difficile-Associated Diarrhea:** Evaluate patients if diarrhea occurs. (5.6)
- **Neutropenia:** Periodically monitor leukocyte count. (5.8)
- **Phlebitis:** To reduce the risk of local irritation and phlebitis administer Vancomycin Injection by a secure intravenous route of administration. (5.9)
- **Development of Drug-Resistant Bacteria:** Prescribing Vancomycin Injection in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug resistant bacteria. (5.10)

ADVERSE REACTIONS

The common adverse reactions are anaphylaxis, "red man syndrome", acute kidney injury, hearing loss, neutropenia. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Xellia Pharmaceuticals USA, LLC at 1-833-295-6953 or FDA at 1-800-FDA-1088 or 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)

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