NOW 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 pregnancy.
Please see Important Safety Information including boxed warning on reverse.

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VANCO READY™

VANCOMYCIN INJECTION, USP

READY TO INFUSE

Product Name : *VANCO READY™* (Vancomycin Injection Premix, 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

Order *VANCO READY™* CLICK HERE

INDICATIONS AND USAGE

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

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF EMBRYO-FETAL TOXICITY DUE TO EXCIPIENTS

See full prescribing information for complete boxed warning. This formulation of Vancomycin Injection, USP is not recommended for use during pregnancy because it contains the excipients polyethylene glycol (PEG 400) and N-acetyl D-alanine (NADA), which caused fetal malformations in animal reproduction studies. If use of vancomycin is needed during pregnancy, use other available formulations of vancomycin. (5.1, 8.1)

DOSAGE AND ADMINISTRATION

Use this formulation of Vancomycin Injection, USP 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, USP 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, USP 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)

Clostridium Difficile-Associated Diarrhea: Evaluate patients if diarrhea occurs. (5.5)

• Neutropenia: Periodically monitor leukocyte count. (5.7)

• Phlebitis: To reduce the risk of local irritation and phlebitis administer Vancomycin Injection, USP by a secure intravenous route of administration. (5.8)

Development of Drug-Resistant Bacteria: Prescribing Vancomycin Injection, USP 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. (5.9)

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)

XEL-115

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