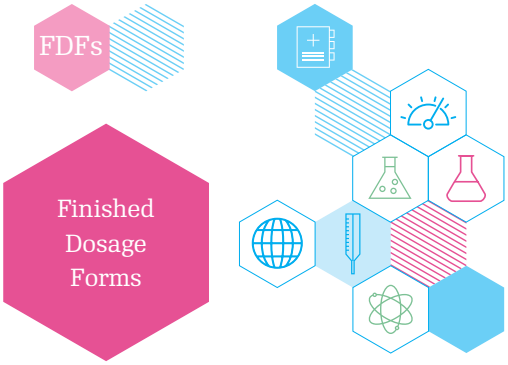
xellia PHARMACEUTICALS



Vancomycin Injection, Ready to Use

Vancomycin hydrochloride is a glycopeptide antibiotic active against a wide variety of gram-positive bacteria, most important being staphylococci, such as *Staphylococcus aureus* and *Staphylococcus epidermidis* (including susceptible methicillin-resistant strains), but also active against corynebacterium, enterococci, (e.g. *Enterococcus faecalis*), *Streptococcus bovis* and viridans group streptococci [1].

Indication: Used in the treatment of severe systemic methicillin resistant (MRSA) and sensitive strains where other antibiotics cannot be used due to intolerance or drug resistance; including septicemia, infective endocarditis, skin and skin structure infections, bone infections and lower respiratory tract infections.

Application: Administered systemically as intravenous infusions.

		Packaging configuration
Presentations	500 mg	Carton of twelve 500 mg/100 mL bags
	750 mg	Carton of twelve 750 mg/150 mL bags
	1 g	Carton of twelve 1 g/200 mL bags
	1.25 g	Carton of six 1.25 g/250 mL bags
	1.5 g	Carton of six 1.5 g/300 mL bags
	1.75 g	Carton of six 1.75 g/350 mL bags
	2 g	Carton of six 2 g/400 mL bags
Compliance	USP*	
Manufacturing site	CMO for Xellia Pharmaceuticals ApS Xellia Pharmaceuticals, Cleveland, USA	
Release site	CMO for Xellia Pharmaceuticals ApS	
Site registered	US FDA EU GMP issued by the Swiss authorities	
Regulatory documentation	New Drug Application US	

	CMO	Cleveland
Batch size	100 mL: 60.500 bags 150 mL: between 46.000 and 64.000 bags 200 mL: between 45.000 and 49.000 bags 250 mL: between 36.000 and 39.200 bags 300 mL: between 31.200 and 32.800 bags 350 mL: between 26.400 and 28.000 bags 400 mL: between 23.200 and 24.800 bags	100 mL: 45.000 bags 150 mL: 30.000 bags 200 mL: 22.000 bags 250 mL: 18.000 bags 300 mL: 15.000 bags 350 mL: 13.000 bags 400 mL: 11.000 bags

Packaging material	Primary: Single-dose flexible bags in sealed aluminum overpouch Secondary: Carton box with leaflet and 6 or 12 overpouches
Shelf-life	16 months in overpouch
Storage conditions	Store below 25°C (77°F) Product should be used within 28 days of removal from aluminum overpouch

*Vancomycin Injection, USP is approved for use only in the US.
It is not to be used during the first and second trimesters of pregnancy. Please see important safety information below.
For full prescribing information, including boxed warning, please visit xellia.com/us/vancoready.
Licensing and distributor opportunities are available outside the US.

INTERNATIONAL SALES OFFICE: Xellia Pharmaceuticals ApS, Copenhagen, Denmark
Tel: +45 32 64 55 00 E-mail: info.dk@xellia.com

LOCAL SALES OFFICES:
www.xellia.com/contact

A company owned by Novo Holding A/S
www.xellia.com

Product sheet release date: September 14th, 2023
[1] *Vancomycin Injection Prescribing Information 10/2021*

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)

See 17 for patient counselling information.

Revised: 10/2021