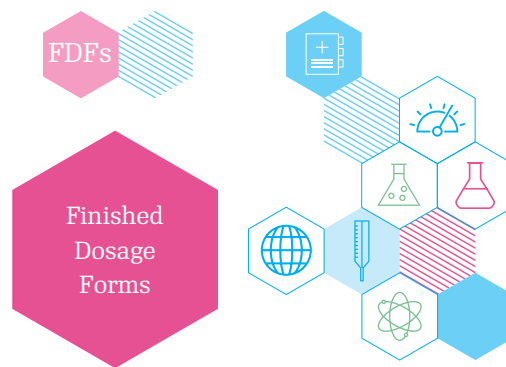


Vancomycin HCl vials



Vancomycin hydrochloride (HCl) is a glycopeptide antibiotic active against a wide variety of aerobic Gram-positive bacteria, most important being staphylococci, including *Staphylococcus aureus* and *Staphylococcus epidermidis* (including heterogeneous methicillin-resistant strains), but also active against diphtheroids, enterococci, (e.g. *Enterococcus faecalis*), *Streptococcus bovis* and viridans group streptococci.

Indication: Used in the treatment of patients with severe and/or methicillin-resistant staphylococcal infections (endocarditis, bone infections, lower respiratory tract infections, septicemia and skin structure infections) and treatment of preoperative prophylaxis of streptococcal or diphtheroid endocarditis where other antibiotics cannot be used due to intolerance or drug resistance. It may be administered orally for treatment of antibiotic-associated pseudomembranous colitis produced by *C. difficile* and for staphylococcal enterocolitis.

Application: Administered as intravenous infusions for systemic therapy. May be administered orally for treatment of antibiotic-associated pseudomembranous colitis.

Dosage form	Lyophilized vials			
Strength	0.5 g (Copenhagen) 1 g (Copenhagen) 5 g for US only (Copenhagen) 10 g for US only (Copenhagen)			
Compliance	USP Currently no monograph in Ph. Eur. for vancomycin vials The active ingredient vancomycin hydrochloride complies with Ph. Eur. and USP			
Manufacturing site	Xellia Pharmaceuticals ApS, Copenhagen, Denmark			
Release site	Xellia Pharmaceuticals ApS, Copenhagen, Denmark			
Site registered	EU GMP issued by Danish Medicines Agency (Xellia Copenhagen) US FDA (Xellia Copenhagen) Other health authorities			
Regulatory documentation	US dossier RoW* dossier			
Batch size	0.5 g	1 g	5 g for US only	10 g for US only
	Copenhagen 80000 vials	Copenhagen 51000 vials	Copenhagen 8100 vials	Copenhagen 8300 vials
Packaging sizes	1 vial/pack 10 vials/pack 25 vials/pack		1 vial/pack	
	Possibility for different packaging configuration as well as option for unlabelled vial supply can be discussed with your Sales Representative			
Shelf-life	24 months			
Storage conditions	Between 15-25°C (59-77°F) depending on territory			

*Rest of the World