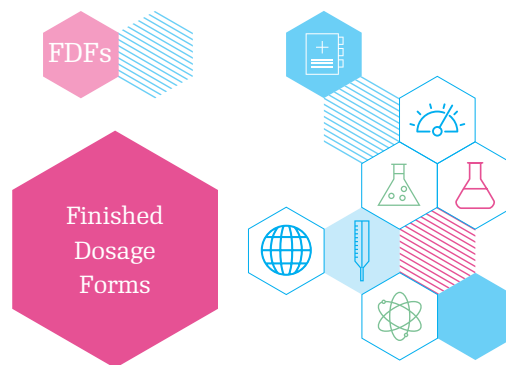


# Vancomycin HCl vials



**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, skin and skin structure infections) and treatment of preoperative prophylaxis of streptococcal or diptheroid 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 and staphylococcal enterocolitis.

<b>Dosage form</b>	Lyophilized vials			
<b>Strength</b>	0.5 g 1 g 5 g 10 g			
<b>Compliance</b>	USP Currently no monograph in Ph. Eur. for vancomycin vials The active ingredient vancomycin hydrochloride complies with Ph. Eur. and USP			
<b>Manufacturing site</b>	Xellia Pharmaceuticals ApS, Copenhagen, Denmark Xellia Pharmaceuticals, Cleveland, USA			
<b>Release site</b>	Xellia Pharmaceuticals ApS, Copenhagen, Denmark Xellia Pharmaceuticals, Cleveland, USA			
<b>Site registered</b>	EU GMP issued by Danish Medicines Agency (Xellia Copenhagen) US FDA (Xellia Copenhagen & Xellia Cleveland) Other health authorities (Xellia Copenhagen)			
<b>Regulatory documentation</b>	US dossier RoW* dossier			
<b>Batch size</b>	<b>0.5 g</b>	<b>1 g</b>	<b>5 g (US only)</b>	<b>10 g (US only)</b>
	<b>Copenhagen</b> 80000 vials	<b>Copenhagen</b> 51000 vials	<b>Copenhagen</b> 8100 vials	<b>Copenhagen</b> 8300 vials
		<b>Cleveland</b> 61300 vials	<b>Cleveland</b> 18300 vials	<b>Cleveland</b> 9100 vials
<b>Packaging sizes</b>	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			
<b>Shelf-life</b>	24 months			
<b>Storage conditions</b>	Between 15-25°C (59-77°F) depending on territory			

\*Rest of the World