

Vancomycin hydrochloride

Vancomycin hydrochloride is a glycopeptide antibiotic active against a wide variety of 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 lower respiratory tract infections, septicemia, bone, skin and skin structure infections, and infective endocarditis due to severe systemic methicillin resistant (MRSA) and sensitive strains where other antibiotics cannot be used because of intolerance or drug resistance. May be administered orally for treating antibiotic-associated pseudomembranous colitis produced by *Clostridium difficile* and for staphylococcal enterocolitis.

Application: Administered systemically as intravenous infusions and as capsules for oral administration. IV form can also be used orally for the treatment of antibiotic-associated pseudomembranous colitis and staphylococcal enterocolitis.

Product grades	Sterile, non-micronized	Non-sterile, non-micronized
Compliance Ph. Eur.	Ph. Eur. USP	
Manufacturing site	Xellia Pharmaceuticals ApS, Copenhagen, Denmark	
Release site	Xellia Pharmaceuticals ApS, Copenhagen, Denmark	
Site registered	EU GMP issued by Danish Medicines Agency US FDA Other health authorities	
Regulatory documentation	EU Drug Master File (DMF)/Certificate of Suitability (CEP) US Drug Master File (DMF) Japan Drug Master File (JDMF) Vancomycin hydrochloride – sterile DMF available in selected markets outside US/EU/Japan	
Packaging sizes	Sterile, non-micronized 0.5 kgA* 3 kgA* 8 kgA*	Non-sterile, non-micronized 0.5 kgA* 3 kgA* 8 kgA* 10 kgA*
Packaging material	Sterile, non-micronized Primary: Aluminum containers with PE insert and polypropylene lid Secondary: Polystyrene	Non-sterile, non-micronized Primary: Aluminum containers with PE insert and polypropylene lid Secondary: Polystyrene
Shelf-life	2 years (according to Ph. Eur.) 3 years (according to USP)	
Storage conditions	Store refrigerated (2–8°C/36–46°F)	

*Kilogram Activity