

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	Non-sterile, non-micronized
Compliance	Ph. Eur. USP CP
Manufacturing site	Xellia (Taizhou) Pharmaceuticals Co., Ltd., China
Release site	Xellia (Taizhou) Pharmaceuticals Co., Ltd., China
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) China Drug Master File (CDMF) DMF also available in other selected countries outside EU/US/China
Packaging sizes	2.5 kg 8 kg 10 kg
Packaging material	Primary: Aluminum foil bag (double sealed) Secondary: Plastic cardboard box
Shelf-life	2 years (according to Ph. Eur.) 3 years (according to USP)
Storage conditions	Store refrigerated (2-8°C/36-46°F)
Other Documentation	Written confirmation for import into EU Chinese Manufacturing License (Taizhou Site)