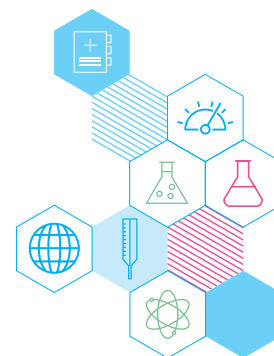


Vancomycin hydrochloride



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.

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|---------------------------------|---|---|
| Product grades | Sterile, non-micronized | Non-sterile, non-micronized |
| Compliance | 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) Vancomycin hydrochloride – sterile DMF available in selected markets outside US/EU | |
| 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