

Daptomycin vials

Daptomycin is a lipopeptide antibacterial agent active against gram-positive bacteria.

Indication: Used in the treatment of complicated skin and skin structure/soft-tissue infections caused by susceptible isolates of gram-positive bacteria such as *Staphylococcus aureus* (including MRSA-methicillin-resistant *Staphylococcus aureus*), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae* *supsp. equisimilis* and *Enterococcus faecalis* (vancomycin-susceptible isolates only). Additionally used for bloodstream infections (bacteremia), including patients with right-sided infective endocarditis caused by *Staphylococcus aureus*.

Application: Administered as intravenous infusions or injections.

Dosage form	Lyophilized vials	
Strength	350 mg 500 mg	
Compliance	No monograph for daptomycin in either Ph. Eur. or USP available	
Manufacturing site	CMO for Xellia Pharmaceuticals ApS Xellia Pharmaceuticals ApS, Copenhagen, Denmark (for US only)	
Release site	CMO for Xellia Pharmaceuticals ApS Xellia Pharmaceuticals ApS, Copenhagen, Denmark	
Site registered	EU GMP issued by Danish Medicines Agency US FDA Other health authorities	
Regulatory documentation	EU dossier US dossiers RoW* dossier	
Batch size	350 mg EU: 32150 vials US: 32150 and 40000 vials	500 mg EU: 22000 vials US: 33400, 42000 and 53500 vials
Packaging sizes	1 vial/pack	
Shelf-life	36 months	
Storage conditions	Between 2-8°C (36-46°F)	

*Rest of the World