

Daptomycin RT 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	
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 (filing Q1, 2024) US dossier	
Batch size	350 mg 40,789 vials	500 mg 42,592 vials
Packaging sizes	1 vial/pack	
Shelf-life	24 months	
Storage conditions	EU dossier: Store below 25°C (77°F) US dossier: Between 20-25°C (68-77°F)	