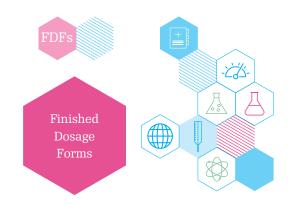


Daptomycin RT vials



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		
	USFDA		
	Other health authorities		
Regulatory	EU dossier (filing Q1, 2024)		
documentation	US dossier		
Batch size	350 mg	500 mg	
	40,789 vials	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)		