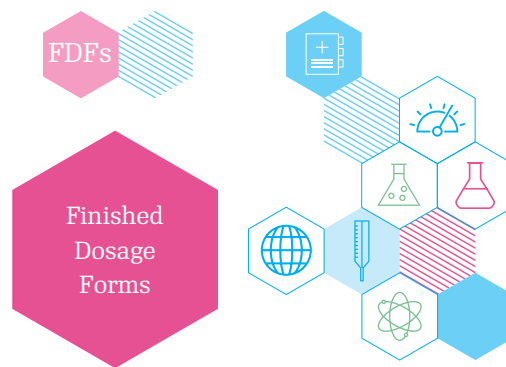


# Daptomycin vials



**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* *subsp. 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.

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

\* Products protected by valid patents are not offered for sale in countries, where the sale of such products constitutes a patent infringement.

\*\* Rest of the World