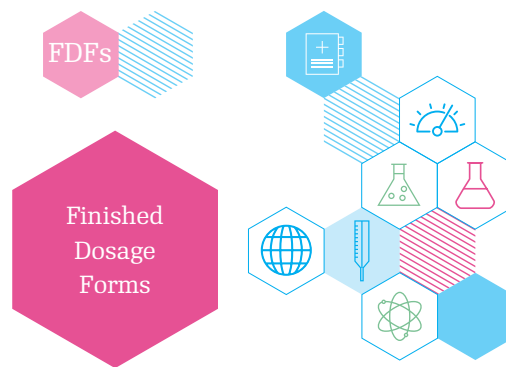


# Daptomycin vials



**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<br>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<br>Xellia Pharmaceuticals ApS, Copenhagen, Denmark |  |
| <b>Release site</b>             | CMO for Xellia Pharmaceuticals ApS<br>Xellia Pharmaceuticals ApS, Copenhagen, Denmark |  |
| <b>Site registered</b>          | EU GMP issued by Danish Medicines Agency<br>US FDA<br>Other health authorities        |  |
| <b>Regulatory documentation</b> | EU dossier<br>US dossiers<br>RoW* dossier   |  |
| <b>Batch size</b>               | <b>350 mg</b><br>EU: 32150 vials<br>US: 32150 and 40000 vials                         | <b>500 mg</b><br>EU: 22000 vials<br>US: 33400, 42000 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)   |  |

\*Rest of the World