

Daptomycin

Daptomycin is a lipopeptide antibiotic active against gram-positive bacteria such as *Staphylococcus aureus* (including methicillin resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae* subsp. *equisimilis*, and *Enterococcus faecalis* (vancomycin-susceptible isolates only).

Indication: Used in the treatment of complicated skin and skin structure/soft-tissue infections caused by susceptible isolates of gram-positive bacteria in adult and pediatric patients and in the treatment of patients with *Staphylococcus aureus* (including MRSA-methicillin-resistant strains) bacteremia, as well as right-sided endocarditis in adults.

Application: Administered systemically as intravenous infusion or injection.

Product grades	Non-sterile
Compliance	No monograph for daptomycin in either Ph. Eur. or USP available
Manufacturing site	CMO for Xellia Pharmaceuticals ApS
Release site	Testing site: Xellia Pharmaceuticals Ltd., Budapest, Hungary Release site: Xellia Pharmaceuticals Private Limited, Hyderabad, India
Site registered	US FDA approved
Regulatory documentation	US Drug Master File (DMF) DMF also available in other selected countries
Packaging sizes	2 kg, alternative packaging size can be discussed with Sales Representative
Packaging material	Primary Packaging: The final product is packaged in 2-ply polyethylene bags under vacuum and heat-sealed. Secondary Packaging: The product is then packaged in aluminium foil bag and heat-sealed. Tertiary Packaging: The product is then placed in aluminium container and sealed.
Shelf-life	3 years
Storage conditions	2 - 8°C