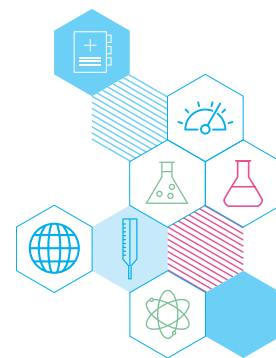


Daptomycin

APIs

Active
Pharmaceutical
Ingredients



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.

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	Xellia Pharmaceuticals Ltd., Budapest, Hungary
Release site	Xellia Pharmaceuticals Ltd., Budapest, Hungary
Site registered	EU GMP issued by Hungarian National Institute of Pharmacy recognized by FDA from March 1st 2018 according to Mutual Recognition Agreement (MRA)
Regulatory documentation	US Drug Master File (DMF) EU Drug Master File (DMF) China Drug Master File (CDMF) DMF also available in other selected countries outside EU/US/China
Packaging sizes	Packaging size can be discussed with your Sales Representative
Packaging material	Primary: Aluminum foil bag (laminated with Polyethylene on the inner side and Polyester on outer side) and heat-sealed Secondary: Primary bag placed into second identical bag also heat-welded and labelled
Shelf-life	3 years
Storage conditions	Store in a freezer (-20±5°C / 5 to -13°F)