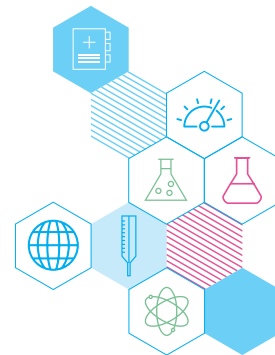


Amphotericin B

APIs

Active
Pharmaceutical
Ingredients



Amphotericin B is a mixture of polyenes active against a wide variety of fungi e.g. *Aspergillus*, *Candida* and *Cryptococcus* species.

Indication: Used in the treatment of severe, invasive, potentially life-threatening fungal infections (mycosis) typically in immunocompromised patients.

Applications: Administered intravenously as a colloidal complex with sodium deoxycholate or as a liposomal formulation. The low germ and endotoxin content makes Xellia's amphotericin B particularly suitable for parenteral use.

Product grades	Non-sterile
Compliance	Ph. Eur. USP JP CP
Manufacturing site	Xellia Pharmaceuticals ApS, Copenhagen, Denmark
Release site	Xellia Pharmaceuticals ApS, Copenhagen, Denmark
Site registered	EU GMP issued by Danish Medicines Agency US FDA Other health authorities
Regulatory documentation	EU Drug Master File (DMF)/Certificate of Suitability (CEP) US Drug Master File (DMF) China Drug Master File (CDMF) Japan Drug Master File (JDMF) DMF also available in other selected countries outside EU/US/China
Packaging sizes	0.1 kgA* 0.5 kgA* 1 kgA*
Packaging material	Primary: Polyethylene bag, with plastic seal Secondary: Two polyethylene bags, heat sealed Tertiary: Aluminum container
Shelf-life	2 years
Storage conditions	Store refrigerated (2-8°C/ 36-46°F)

*Kilogram Activity