

# Amphotericin B

**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.

<b>Product grades</b>	Non-sterile
<b>Compliance</b>	Ph. Eur. USP JP CP
<b>Manufacturing site</b>	Xellia Pharmaceuticals ApS, Copenhagen, Denmark
<b>Release site</b>	Xellia Pharmaceuticals ApS, Copenhagen, Denmark
<b>Site registered</b>	EU GMP issued by Danish Medicines Agency US FDA Other health authorities
<b>Regulatory documentation</b>	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/Japan
<b>Packaging sizes</b>	0.1 kgA* 0.5 kgA* 1 kgA*
<b>Packaging material</b>	Primary: Polyethylene bag, with plastic seal Secondary: Two polyethylene bags, heat sealed Tertiary: Aluminum container
<b>Shelf-life</b>	2 years
<b>Storage conditions</b>	Store refrigerated (2-8°C/ 36-46°F)

\*Kilogram Activity