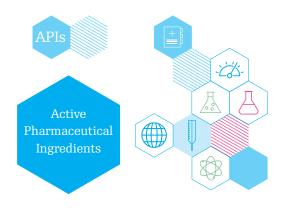


Bacitracin zinc



Bacitracin zinc is composed of a group of polypeptides with antibiotic activity against a variety of gram-positive bacteria including staphylococci. The zinc complex adds stability to the component, making bacitracin zinc more stable compared to bacitracin.

Indication: Used in the treatment of local infections, mainly infections of the skin, ear and eye.

Application: Administered locally as a combination drug product used in powders, ointments and solutions.

Product grades	Sterile, micronized No	Non-sterile, micronized No		Non-sterile, non-micronized
Compliance	Ph. Eur. USP			
Manufacturing site	Xellia (Taizhou) Pharmaceuticals Co., Ltd., China (non-sterile) CMO for sterilisation only			
Release site	Xellia (Taizhou) Pharmaceuticals Co., Ltd., China (non-sterile) Xellia Pharmaceuticals ApS, Copenhagen, Denmark (sterile)			
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) - non-sterile only US Drug Master File (DMF) DMF also available in other selected countries outside EU/US			
Packaging sizes	Sterile micronized		Non-sterile micronized & non-micronized	
	750 g	ī	l kg 5 kg 15 kg	
Packaging material	Sterile micronized		Non-sterile micronized & non-micronized	
	Primary: Aluminum container with butyl lid and tear-off aluminum sea Secondary: Polystyrene	al g		yethylene bag closed with cable tie Heat sealed multi-layer laminated ng
Shelf-life	Non-sterile: 5 years Sterile: Ph. Eur. (36 months), USP (48 months)			
Storage conditions	Do not store above 25 °C (77 °F)			
Other documentation	Written confirmation for import into EU Chinese Manufacturing License (Taizhou Site)			