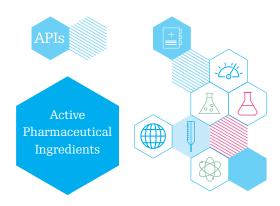


Bacitracin zinc



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 Nor	n-sterile, micronized	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	Non-sterile		
	micronized	micronized	micronized & non-micronized	
	750 g	1kg	1kg	
		5 kg		
		15 kg		
Packaging material	Sterile	Non-sterile	2	
	micronized	micronized	l & non-micronized	
	Primary: Aluminum container with r		blyethylene bag closed with cable tie	
	butyl lid and tear-off aluminum sea	Jecondar y	: Heat sealed multi-layer laminated	
	Secondary: Polystyrene	aluminum b	oag	
Shelf-life 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)			