

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	Non-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 micronized	Non-sterile micronized & non-micronized	
	750 g	1 kg 5 kg 15 kg	
Packaging material	Sterile micronized	Non-sterile micronized & non-micronized	
	Primary: Aluminum container with reinforced butyl lid and tear-off aluminum seal Secondary: Polystyrene	Primary: Polyethylene bag closed with cable tie Secondary: Heat sealed multi-layer laminated aluminum bag	
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)		