



# 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.

<b>Product grades</b>	Sterile, micronized	Non-sterile, micronized	Non-sterile, non-micronized
<b>Compliance</b>	Ph. Eur. USP		
<b>Manufacturing site</b>	Xellia (Taizhou) Pharmaceuticals Co., Ltd., China (non-sterile) CMO for sterilisation only		
<b>Release site</b>	Xellia (Taizhou) Pharmaceuticals Co., Ltd., China (non-sterile) Xellia Pharmaceuticals ApS, Copenhagen, Denmark (sterile)		
<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) - non-sterile only US Drug Master File (DMF) DMF also available in other selected countries outside EU/US		
<b>Packaging sizes</b>	<b>Sterile micronized</b>	<b>Non-sterile micronized &amp; non-micronized</b>	
	750 g	1 kg 5 kg 15 kg	
<b>Packaging material</b>	<b>Sterile micronized</b>	<b>Non-sterile micronized &amp; non-micronized</b>	
	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	
<b>Shelf-life</b>	Non-sterile: 5 years Sterile: Ph. Eur. (36 months), USP (48 months)		
<b>Storage conditions</b>	Do not store above 25 °C (77 °F)		
<b>Other documentation</b>	Written confirmation for import into EU Chinese Manufacturing License (Taizhou Site)		