xellia PHARMACEUTICALS

APIs
Active Pharmaceutical Ingredients

Bacitracin

Bacitracin is composed of a group of polypeptides with antibiotic activity against many Gram-positive bacteria including staphylococci, streptococci and clostridia.

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

Application: Administered, typically as a combination drug product used in; topical creams, powders and solutions, ophthalmic ointments, otic solutions and solutions for irrigation of wounds. Bacitracin is also administered systemically as intramuscular injections and orally as lozenges.

Product grades	Sterile, non-micronized Non-sterile, micronized Non-sterile, non-micronized	
Compliance	Ph. Eur. USP	
Manufacturing site	Xellia Pharmaceuticals Ltd, Taizhou, China (non-sterile) Xellia Pharmaceuticals ApS, Copenhagen, Denmark (sterilisation only)	
Release site	Xellia Pharmaceuticals Ltd, Taizhou, China (non-sterile) Xellia Pharmaceuticals ApS, Copenhagen, Denmark (sterile)	
Site registered	EU GMP issued by Danish Medicines Agency US FDA	
Regulatory documentation	EU Drug Master File (DMF) Certificate of Suitability (CEP) – non-sterile only US Drug Master File (DMF) Letter of Access (LoA)	
Packaging sizes	**Sterile** **Non-Micronised**	**Non-sterile** **Micronised & Non-Micronised**
	2 kg (approx. 150 MU*)	1 kg 5 kg 15 kg
Packaging material	**Sterile** **Non-Micronised**	**Non-sterile** **Micronised & Non-Micronised**
	Primary: Aluminum container with reinforced butyl lid and tear-off aluminum seal Secondary: Polystyrene	Primary: Polyethylene bag Secondary: Heat sealed multi-layer laminated aluminum bag
Shelf-life	Non-sterile: 4 years Sterile: 3 years	
Storage conditions	Below 8°C (46°F)	
Other documentation	Written confirmation for import into EU Chinese Manufacturing License	

*Million Units

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LOCAL SALES OFFICES AND GLOBAL TECHNICAL SUPPORT:
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A company owned by Novo Holdings A/S
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