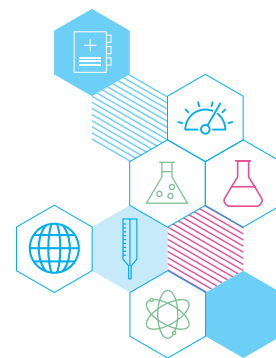


Bacitracin



Bacitracin is composed of a group of polypeptides with antibiotic activity against a variety of Gram-positive bacteria including staphylococci.

Indication: Used locally for the treatment of infections of the skin, ear and eye or for intramuscular use in infants for the treatment of pneumonia and empyema caused by susceptible staphylococci in some parts of the world (e.g. Canada).

Application: Administered typically as a combination drug product used in topical creams, powders, ointments and solutions. Bacitracin is also administered systemically as intramuscular injections in some parts of the world (e.g. Canada).

Product grades	Sterile, non-micronized	Non-sterile, micronized	Non-sterile, non-micronized
Compliance	Ph. Eur. USP		
Manufacturing site	Xellia (Taizhou) Pharmaceuticals Co., Ltd., China (non-sterile) Xellia Pharmaceuticals ApS, Copenhagen, Denmark (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		
Regulatory documentation	EU Drug Master File (DMF)/Certificate of Suitability (CEP) US Drug Master File (DMF) Letter of Access (LoA)		
Packaging sizes	Sterile non-micronized	Non-sterile micronized & non-micronized	
	750 g 2 kg	1 kg 5 kg 15 kg	
Packaging material	Sterile non-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: 4 years Sterile: 3 years		
Storage conditions	Below 8°C (46°F)		
Other documentation	Written confirmation for import into EU Chinese Manufacturing License (Taizhou site)		