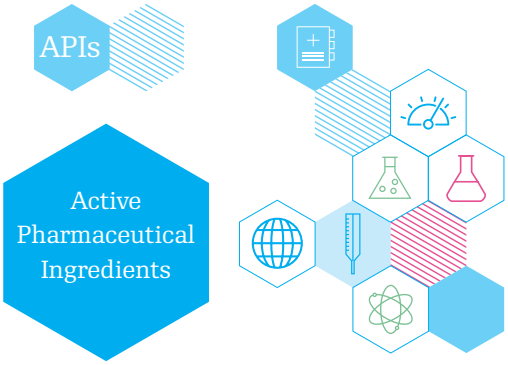
xellia PHARMACEUTICALS



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 locally as a combination drug product used in 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 JP CP		
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 Other health authorities		
Regulatory documentation	EU Drug Master File (DMF)/Certificate of Suitability (CEP) US Drug Master File (DMF) China Drug Master File (CDMF for non-sterile grade) Japan Drug Master File (JDMF for non-sterile grade) DMF also available in other selected countries outside EU/US/China		
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	Store refrigerated (2-8°C/ 36-46°F)		
Other documentation	Written confirmation for import into EU Chinese Manufacturing License (Taizhou Site)		

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LOCAL SALES OFFICES:
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A company owned by Novo Holding A/S
www.xellia.com

Product sheet release date: June 13th, 2023

XEL-394