xellia PHARMACEUTICALS

Active Pharmaceutical Ingredients

# 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, micronized | Non-sterile, micronized | Non-sterile, non-micronized |
|---|---|---|---|
| Compliance | Ph. Eur.<br>USP<br>JP<br>CP | | |
| Manufacturing site | Xellia (Taizhou) Pharmaceuticals Co., Ltd., China (non-sterile)<br>Xellia Pharmaceuticals ApS, Copenhagen, Denmark (sterilisation only) | | |
| Release site | Xellia (Taizhou) Pharmaceuticals Co., Ltd., China (non-sterile)<br>Xellia Pharmaceuticals ApS, Copenhagen, Denmark (sterile) | | |
| Site registered | EU GMP issued by Danish Medicines Agency<br>US FDA<br>Other health authorities | | |
| Regulatory documentation | EU Drug Master File (DMF)/Certificate of Suitability (CEP)<br>US Drug Master File (DMF)<br>China Drug Master File (CDMF for non-sterile grade)<br>Japan Drug Master File (JDMF for non-sterile grade)<br>DMF also available in other selected countries outside EU/US/China | | |
| Packaging sizes | Sterile micronized | Non-sterile micronized & non-micronized | |
| | 750 g<br>2 kg | 1 kg<br>5 kg<br>15 kg | |
| Packaging material | Sterile micronized | Non-sterile micronized & non-micronized | |
| | Primary: Aluminum container with reinforced butyl lid and tear-off aluminum seal<br>Secondary: Polystyrene | Primary: Polyethylene bag closed with cable tie<br>Secondary: Heat sealed multi-layer laminated aluminum bag | |
| Shelf-life | Non-sterile: 4 years<br>Sterile: 3 years | | |
| Storage conditions | Store refrigerated (2-8°C/ 36-46°F) | | |
| Other documentation | Written confirmation for import into EU<br>Chinese Manufacturing License (Taizhou Site) | | |

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