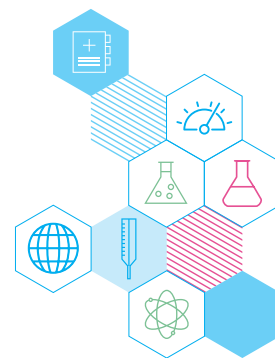


# Gramicidin

APIs

Active  
Pharmaceutical  
Ingredients



**Gramicidin** is a mixture of linear polypeptides active against a variety of Gram-positive bacteria.

**Indication:** Ophthalmic solution is indicated for the topical treatment of superficial infections of the external eye and its adnexa caused by susceptible bacteria, such as conjunctivitis, keratitis and keratoconjunctivitis, blepharitis and blepharoconjunctivitis. Medicinal lozenges and spray are indicated for throat inflammatory infections. The topical cream can be used to treat certain skin infections and to prevent infections in burns, skin grafts, minor cuts, and wounds.

**Application:** Formulated alone or as a combination drug product used in ophthalmic solutions, medicinal lozenges and spray for sore throat and as a topical antibiotic for the treatment of skin infections.

|                          |   |
|--------------------------|---|
| Product grades           | Non-sterile   |
| Compliance               | Ph. Eur.<br>USP   |
| Manufacturing site       | Xellia Pharmaceuticals Ltd., Budapest, Hungary  |
| Release site             | Xellia Pharmaceuticals Ltd., Budapest, Hungary  |
| Site registered          | EU GMP issued by Hungarian National Institute of Pharmacy<br>US FDA   |
| Regulatory documentation | EU Drug Master File (DMF)/Certificate of Suitability (CEP)<br>US Drug Master File (DMF)<br>Letter of Access (LoA)         |
| Packaging sizes          | 100 g<br>500 g  |
| Packaging material       | Primary: Polyethylene bag closed with twist tie plastic clip<br>Secondary: Heat sealed multi-layer laminated aluminum bag |
| Shelf-life               | 3 years   |
| Storage conditions       | Below 25°C (77°F)   |