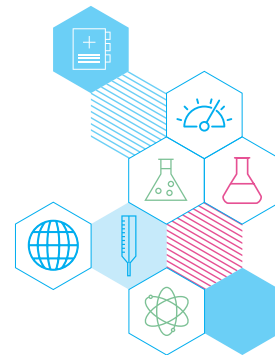


Gramicidin

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. Otic solution can be used to treat infection or inflammation of the ear.

Application: Formulated alone or as a combination drug product used in otic, 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. 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 recognized by FDA from March 1st 2018 according to Mutual Recognition Agreement (MRA)
Regulatory documentation	EU Drug Master File (DMF)/Certificate of Suitability (CEP) US Drug Master File (DMF) DMF also available in other selected countries outside EU/US
Packaging sizes	100 g 500 g
Packaging material	Primary: Polyethylene bag closed with twist tie plastic clip Secondary: Heat sealed multi-layer laminated aluminum bag
Shelf-life	3 years
Storage conditions	Do not store above 25°C (77°F)