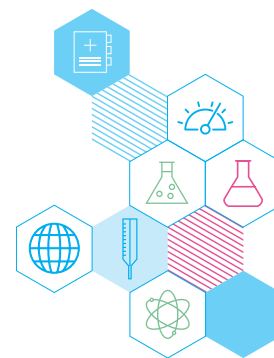


Colistin sulfate

APIs

Active
Pharmaceutical
Ingredients



Colistin sulfate is a mixture of sulfates of polypeptide antibiotics active against Gram-negative bacteria including *Pseudomonas aeruginosa*, *Enterobacter aerogenes*, *Escherichia coli* and *Klebsiella pneumoniae*.

Indication: Used in the treatment of acute infections due to sensitive strains of Gram-negative pathogens.

Application: Administered topically in the treatment of local infections, mainly external ear infections. Often formulated as otic suspensions and solutions.

Product grades	Non-sterile, non-micronized
Compliance	Ph. Eur. USP
Manufacturing site	Xellia Pharmaceuticals ApS, Copenhagen, Denmark
Release site	Xellia Pharmaceuticals ApS, Copenhagen, Denmark
Site registered	EU GMP certificate US FDA Other health authorities
Regulatory documentation	EU Drug Master File (DMF)/Certificate of Suitability (CEP) US Drug Master File (DMF) Letter of Access (LoA)
Packaging sizes	10 BOU* 150 BOU*
Packaging material	Primary: Aluminum containers with a polyethylene insert and polypropylene lid Secondary: Polystyrene
Shelf-life	Ph. Eur.: 18 months USP: 60 months
Storage conditions	Below 25°C (77°F)

*Billion Of Units