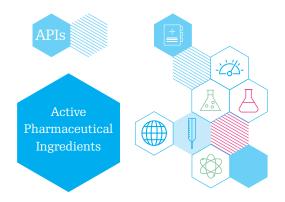


Colistin sulfate



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	EU Drug Master File (DMF)/Certificate of Suitability (CEP)
documentation	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	EU: 36 months
	US: 48 months
Storage conditions	Below 25°C (77°F)

*Billion Of Units