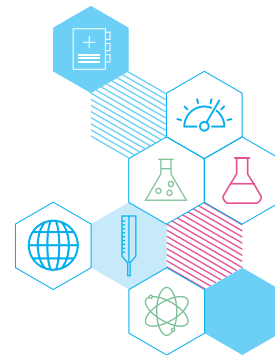


Colistin Sulfate

APIs

Active
Pharmaceutical
Ingredients



Colistin Sulfate is a mixture of the sulfates of polypeptide antibiotics active against Gram-negative bacteria.

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

Application: Colistin Sulfate is administered orally as suspensions or tablets for treatment of intestinal infections. It can also be used for treatment of ear infections.

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 Secondary: Polystyrene
Shelf-life	18 months (according to Ph. Eur.) 5 years (according to USP)
Storage conditions	Below 25°C (77°F)

* BOU = Billions of units.