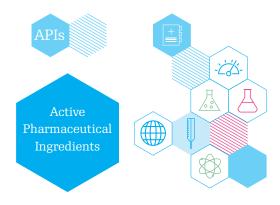


Colistimethate sodium



Colistimethate sodium is a derivative of colistin (polymyxin E) that is a mixture of polypeptide antibiotics active against Gramnegative bacteria, including *Enterobacter aerogenes*, *Escherichia coli*, *Klebsiella pneumoniae* and *Pseudomonas aeruginosa*.

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

Application: Administered systemically as intramuscular injections and intravenous injections or infusions. Colistimethate sodium can also be administered by inhalation or mixed with bone cement, as well used in ophthalmic formulations.

Product grades	Sterile, micronized	Sterile, non-micronized	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 issued by Danish Medicines Agency		
	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	Sterile, micronized	Sterile, non-micronized	Non-sterile, non-micronized
	10 BOU*	15 BOU*	15 BOU*
	100 BOU*	65 BOU*	65 BOU*
Packaging material	Primary: Almuinum containers with polyethylene insert and polypropylene lid		
	Secondary: Polystyrene		
Shelf-life	5 years		
Storage conditions	Below 25°C (77°F)		

*Billion Of Units