

Colistimethate sodium

Colistimethate sodium is a prodrug of colistin (polymyxin E) which is a mixture of polypeptide antibiotics active against gram-negative 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, especially in patients with limited treatment options.

Application: Administered systemically as intramuscular injections and intravenous injections or infusions. Colistimethate sodium can also be administered intrathecally, by intraventricular administration, by inhalation or mixed with bone cement.

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 documentation	EU Drug Master File (DMF) /Certificate of Suitability (CEP) US Drug Master File (DMF) China Drug Master File (CDMF for sterile grade) Japan Drug Master File (JDMF) DMF also available in other selected countries outside EU/US/China/Japan		
Packaging sizes	Sterile, micronized 10 BOU*	Sterile, non-micronized 15 BOU* 65 BOU*	Non-sterile, non-micronized 15 BOU* 65 BOU*
Packaging material	Primary: Aluminum containers with polyethylene insert and polypropylene lid Secondary: Polystyrene		
Shelf-life	5 years		
Storage conditions	Do not store above 25 °C (77 °F)		

*Billion Of Units