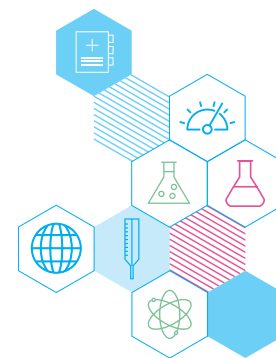


# Colistimethate sodium

APIs

Active  
Pharmaceutical  
Ingredients



**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.

<b>Product grades</b>	Sterile, micronized	Sterile, non-micronized	Non-sterile, non-micronized
<b>Compliance</b>	Ph. Eur. USP		
<b>Manufacturing site</b>	Xellia Pharmaceuticals ApS, Copenhagen, Denmark		
<b>Release site</b>	Xellia Pharmaceuticals ApS, Copenhagen, Denmark		
<b>Site registered</b>	EU GMP issued by Danish Medicines Agency US FDA Other health authorities		
<b>Regulatory documentation</b>	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		
<b>Packaging sizes</b>	<b>Sterile, micronized</b> 10 BOU*	<b>Sterile, non-micronized</b> 15 BOU* 65 BOU*	<b>Non-sterile, non-micronized</b> 15 BOU* 65 BOU*
<b>Packaging material</b>	Primary: Aluminum containers with polyethylene insert and polypropylene lid Secondary: Polystyrene		
<b>Shelf-life</b>	5 years		
<b>Storage conditions</b>	Do not store above 25 °C (77 °F)		

\*Billion Of Units