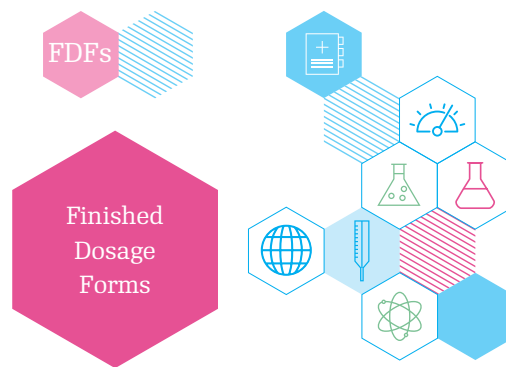


# Colistimethate sodium lyophilized vials



**Colistimethate sodium** is a prodrug of colistin, which is a mixture of polypeptide antibiotics active against gram-negative bacteria, including *Enterobacter aerogenes*, *Escherichia coli*, *Klebsiella pneumoniae* and especially *Pseudomonas aeruginosa*.

**Indication:** Used in the treatment of acute or chronic infections due to sensitive strains of gram-negative pathogens. It is particularly indicated when the infection is caused by sensitive strains of *Pseudomonas aeruginosa*.

**Application:** Administered systemically as intramuscular injections and intravenous injections or infusions.

<b>Dosage form</b>	Lyophilized vials
<b>Strength</b>	150 mg colistin base activity*
<b>Compliance</b>	No monograph for colistimethate sodium vials in Ph. Eur. available USP monograph for colistimethate for injection available
<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
<b>Regulatory documentation</b>	US dossier RoW** dossier
<b>Batch size</b>	80500 vials
<b>Packaging sizes</b>	1 vial/pack 10 vials/pack 12 vials/pack Possibility for different packaging configuration can be discussed with your Sales Representative
<b>Shelf-life</b>	RoW**: 36 months US: 24 months
<b>Storage conditions</b>	Between 15-25°C (59-77°F) depending on territory

\*Equivalent to ~4.5 Million International Units

\*\*Rest of the World