

Colistimethate sodium dry-filled 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 *Pseudomonas aeruginosa*.

Indication: Used in the treatment of patients with serious infections due to selected aerobic gram-negative pathogens with limited treatment options.

Application: Administered intrathecally, by intraventricular administration or as intravenous infusion.

Dosage form	Dry-filled (powder dosed) vials		
Strength	1 MIU* 2 MIU* 3 MIU*		
Compliance	No monograph for colistimethate sodium vials in Ph. Eur. available		
Manufacturing site	Xellia Pharmaceuticals ApS, Copenhagen, Denmark		
Release site	Xellia Pharmaceuticals ApS, Copenhagen, Denmark		
Site registered	EU GMP issued by Danish Medicines Agency Other health authorities		
Regulatory documentation	EU dossier RoW** dossier		
Batch size	1 MIU* vials 600000 vials	2 MIU* vials 400000 vials	3 MIU* vials 200000 vials
Packaging sizes	Labelled vials 1 vial/pack 10 vials/pack 30 vials/pack	Un-labelled vials 150 vials/pack	
	Possibility for different packaging configuration can be discussed with your Sales Representative		
Shelf-life	36 months		
Storage conditions	Below 25°C (77°F)		

* Million International Units
** Rest of the World