

# 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.

<b>Dosage form</b>	Dry-filled (powder dosed) vials		
<b>Strength</b>	1 MIU* 2 MIU* 3 MIU*		
<b>Compliance</b>	No monograph for colistimethate sodium vials in Ph. Eur. 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 Other health authorities		
<b>Regulatory documentation</b>	EU dossier RoW** dossier		
<b>Batch size</b>	<b>1 MIU* vials</b> 600000 vials	<b>2 MIU* vials</b> 400000 vials	<b>3 MIU* vials</b> 400000 vials
<b>Packaging sizes</b>	<b>Labelled vials</b> 1 vial/pack 10 vials/pack 30 vials/pack	<b>Un-labelled vials</b> 150 vials/pack	
	Possibility for different packaging configuration can be discussed with your Sales Representative		
<b>Shelf-life</b>	36 months		
<b>Storage conditions</b>	Below 25°C (77°F)		

\* Million International Units  
\*\* Rest of the World