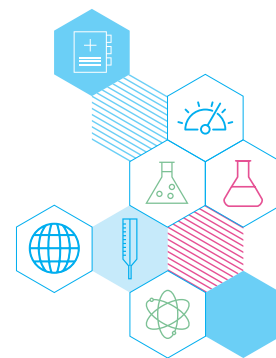


Polymyxin B sulfate



Polymyxin B sulfate is a mixture of sulfates of polypeptide antibiotics active against *Pseudomonas aeruginosa* and other Gram-negative bacteria.

Indication: Used in the treatment of acute urinary, meningeal or blood stream infections due to *Pseudomonas aeruginosa* and other Gram-negative pathogens causing serious infections when less potentially toxic drugs are ineffective or contraindicated. It is often used as a combination drug product for the local treatment of skin, ear and eye infections.

Application: Administered systemically as intravenous infusions, intramuscular or intrathecal injections and locally as eye drops or subconjunctival injections.

Product grades	Sterile, micronized	Sterile, non-micronized	Non-sterile, 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) Letter of Access (LoA)			
Packaging sizes	Sterile		Non-sterile	
	Micronized	Non-micronized	Micronized	Non-micronized
	5 BOU* 10 BOU*	10 BOU*	5 BOU* 10 BOU* 25 BOU*	10 BOU*
Packaging material	Primary: Aluminum containers with PE insert and polypropylene lid Secondary: Polystyrene			
Shelf-life	Sterile for US only: 24 months Sterile & Non-sterile (Ph. Eur./USP grade for ROW): 5 years			
Storage conditions	Below 25°C (77°F)			

*Billion Of Units