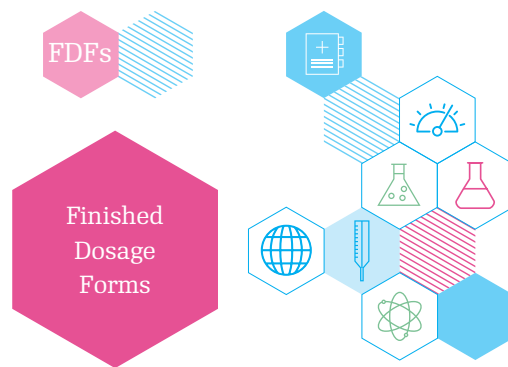


Polymyxin B vials



Polymyxin B is a mixture of the sulfates of polypeptide antibiotics active against almost all gram-negative bacteria except the *Proteus* group.

Indication: Used in the treatment of patients with acute urinary, meningeal or blood-stream infections due to susceptible strains such as *Pseudomonas aeruginosa*, *Haemophilus influenzae*, *Escherichia coli*, *Aerobacter aerogenes* or *Klebsiella pneumoniae*.

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

Dosage form	Lyophilized vials
Strength	500000 units/vial
Compliance	USP
Manufacturing site	CMO for Xellia Pharmaceuticals ApS
Release site	CMO for Xellia Pharmaceuticals ApS
Site registered	US FDA Other health authorities
Regulatory documentation	US dossier RoW* dossier
Batch size	65000 vials
Packaging sizes	1 vial/pack 10 vials/pack 25 vials/pack
Shelf-life	RoW*: 36 months US: 24 months
Storage conditions	Between 15-25 °C (59-77°F)

*Rest of the World

Polymyxin B vial has a boxed warning for use by intrathecal or intramuscular route of administration, where patients must be hospitalized and under constant supervision by physician. In addition, there is risk of nephrotoxicity and neurotoxicity. The safety data on usage in pregnancy is lacking.

For full prescribing information, including boxed warning, please visit:

<https://www.xellia.com/us/products/Polymyxin%20B%20for%20Injection,%20USP>