

# 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.

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