

Active Pharmaceutical Ingredients

Tobramycin sulfate

Tobramycin sulfate is the sulfate salt of tobramycin, an aminoglycoside antibiotic active against gram-negative bacteria including most *Enterobacteriaceae, Pseudomonas aeruginosa* and a few gram-positive bacteria such as *Staphylococcus aureus*.

Indication: Used in the treatment of septicemia (bloodstream infection), infections of the skin, bone, lower respiratory tract, central nervous system, intra-abdominal and complicated recurrent urinary tract infections.

Application: Administered systemically by intramuscular injections or intravenous infusions, locally as ophthalmic solution, conjunctival ointment or by inhalation. Can be mixed with bone cement.

Product grades	Sterile, non-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) US Drug Master File (DMF) DMF also available in other selected countries outside EU/US	
Packaging sizes	Sterile, non-micronized 2.15 kg	Non-sterile, non-micronized 2.15 kg
Packaging material	Sterile, non-micronized Primary: Aluminum containers with PE insert and polypropylene lid Secondary: Polystyrene	Non-sterile, non-micronized Primary: Aluminum containers with PE insert and polypropylene lid Secondary: Polystyrene
Shelf-life	3 years	
Storage conditions	Do not store above 25 °C (77 °F)	

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