



SAGENT Pharmaceuticals™

POLYMYXIN B for Injection, USP

Consider these SAGENT benefits:

- Available in 500,000-unit single-dose vials
- LATEX-FREE
- Preservative-free
- Discover **PreventIV MeasuresSM** packaging features:
 - Easy-to-read drug name and dosage strength
 - Bar codes included on the vials and cartons for ease of scanning
 - Unique label design

Enhanced packaging and labeling designed to promote safety and help reduce medication errors



Please see full prescribing information for POLYMYXIN B for Injection, USP, enclosed.



Discover Injectables Excellence™

POLYMYXIN B for Injection, USP



Innovator Product Name: Polymyxin B for Injection, USP

NDC Number	Description	Strength	Vial Closure	Unit of Sale	Bar Coded
25021-117-10	Glass Vial	500,000 units per vial	20 mm	10 Vials	✓

This SAGENT product meets stringent FDA requirements and is AP rated, LATEX-FREE and preservative-free.

To order, or for more information about discovering Injectables Excellence™ with SAGENT, contact your sales representative, call 1-866-625-1618 or visit www.SagentPharma.com.

Listening. Responding. Delivering. That's Injectables Excellence.™ That's SAGENT Pharmaceuticals.

POLYMYXIN B for Injection, USP

INDICATIONS

Polymyxin B sulfate is a drug of choice in the treatment of infections of the urinary tract, meningitis, and bloodstream caused by susceptible strains of *Pseudomonas aeruginosa*. It may also be used topically and subconjunctivally in the treatment of infections of the eye caused by susceptible strains of *Ps. aeruginosa*.

IMPORTANT SAFETY INFORMATION

WARNING

CAUTION: WHEN THIS DRUG IS GIVEN INTRAMUSCULARLY AND/OR INTRATHECALLY, IT SHOULD BE GIVEN ONLY TO HOSPITALIZED PATIENTS, SO AS TO PROVIDE CONSTANT SUPERVISION BY A PHYSICIAN.

RENAL FUNCTION SHOULD BE CAREFULLY DETERMINED AND PATIENTS WITH RENAL DAMAGE AND NITROGEN RETENTION SHOULD HAVE REDUCED DOSAGE. PATIENTS WITH NEPHROTOXICITY DUE TO POLYMYXIN B SULFATE USUALLY SHOW ALBUMINURIA, CELLULAR CASTS, AND AZOTEMIA. DIMINISHING URINE OUTPUT AND A RISING BUN ARE INDICATIONS FOR DISCONTINUING THERAPY WITH THIS DRUG.

NEUROTOXIC REACTIONS MAY BE MANIFESTED BY IRRITABILITY, WEAKNESS, DROWSINESS, ATAXIA, PERIORAL PARESTHESIA, NUMBNESS OF THE EXTREMITIES, AND BLURRING OF VISION. THESE ARE USUALLY ASSOCIATED WITH HIGH SERUM LEVELS FOUND IN PATIENTS WITH IMPAIRED RENAL FUNCTION AND/OR NEPHROTOXICITY.

THE CONCURRENT OR SEQUENTIAL USE OF OTHER NEUROTOXIC AND/OR NEPHROTOXIC DRUGS WITH POLYMYXIN B SULFATE, PARTICULARLY BACITRACIN, STREPTOMYCIN, NEOMYCIN, KANAMYCIN, GENTAMICIN, TOBRAMYCIN, AMIKACIN, CEPHALORIDINE, PAROMOMYCIN, VIOMYCIN, AND COLISTIN SHOULD BE AVOIDED.

THE NEUROTOXICITY OF POLYMYXIN B SULFATE CAN RESULT IN RESPIRATORY PARALYSIS FROM NEUROMUSCULAR BLOCKADE, ESPECIALLY WHEN THE DRUG IS GIVEN SOON AFTER ANESTHESIA AND/OR MUSCLE RELAXANTS.

USAGE IN PREGNANCY: THE SAFETY OF THIS DRUG IN HUMAN PREGNANCY HAS NOT BEEN ESTABLISHED.

CONTRAINDICATIONS

Polymyxin B for Injection, USP is contraindicated in patients with a prior history of hypersensitivity reactions to polymyxins.

WARNINGS AND PRECAUTIONS

- *Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Polymyxin B for Injection, and may range in severity from mild diarrhea to fatal colitis.
- Baseline renal function should be done prior to therapy, with frequent monitoring of renal function and blood levels of the drug during parenteral therapy.
- Avoid concurrent use of a curariform muscle relaxant and other neurotoxic drugs (ether, tubocurarine, succinylcholine, gallamine, decamethonium and sodium citrate) which may precipitate respiratory depression.
- As with other antibiotics, use of Polymyxin B for Injection may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be instituted.

ADVERSE REACTIONS

- Significant adverse reactions associated with use of Polymyxin B for Injection are nephrotic reactions such as albuminuria, cylindruria, and azotemia. Rising blood levels without any increase in dosage were also seen.
- Significant neurotoxic reactions are facial flushing, dizziness progressing to ataxia, drowsiness, peripheral paresthesias (circumoral and stocking glove), apnea due to concurrent use of curariform muscle relaxants, other neurotoxic drugs or inadvertent overdosage, and signs of meningeal irritation with intrathecal administration.
- Other adverse reactions occasionally reported are drug fever, urticarial rash, pain (severe) at intramuscular injection sites, and thrombophlebitis at intravenous injection sites.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full prescribing information for POLYMYXIN B for Injection, USP.



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