

The Athenex logo is displayed in white script font on a red rectangular background.

Polymyxin B

for Injection, USP

500,000 units per vial | NDC 70860-103-10

ATHENEX AccuraSEESM PACKAGING AND LABELING

**BIG, BOLD AND BRIGHT —
TO HELP YOU SEE IT, SAY IT AND PICK IT RIGHT**

**DIFFERENTIATION IN EVERY LABEL,
DESIGNED TO HELP REDUCE MEDICATION ERRORS**



PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING, FOR POLYMYXIN B FOR INJECTION, USP, ENCLOSED.

THE NEXT GENERATION OF PHARMACY INNOVATION

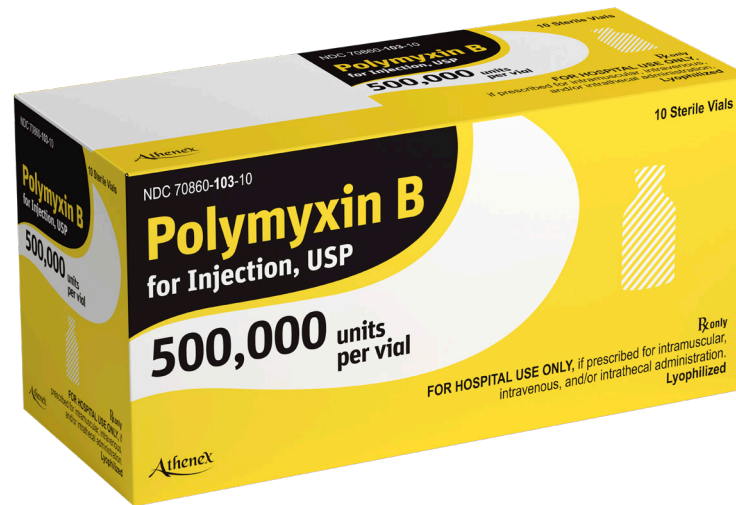
Polymyxin B

for Injection, USP



NDC 70860-103-10
500,000 units per vial

DESCRIPTION	Glass Vial
CONCENTRATION	500,000 units per vial
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes



CHOOSE AccuraSEESM FOR YOUR PHARMACY

Our proprietary, differentiated and highly-visible label designs can assist pharmacists in accurate medication selection.

With a unique AccuraSEE label design for every Athenex product, we're helping your pharmacy to reduce the risk of medication errors. The idea is simple: "So what you see is *exactly* what you get."



POLYMYXIN B for Injection, USP

INDICATION AND USAGE

- Polymyxin B sulfate is a drug of choice in the treatment of infections of the urinary tract, meninges, and bloodstream caused by susceptible strains of *Ps. aeruginosa*.
- It may also be used topically and subconjunctivally in the treatment of infections of the eye caused by susceptible strains of *Ps. aeruginosa*.
- It may be indicated in serious infections caused by susceptible strains of *H. influenzae*, specifically in meningeal infections, *Escherichia coli*, specifically in urinary tract infections, *Aerobacter aerogenes*, specifically in bacteremia and *Klebsiella pneumoniae*, specifically in bacteremia, when less potentially toxic drugs are ineffective or contraindicated.

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 persons with a prior history of hypersensitivity reactions to polymyxins.

WARNINGS

- *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.
- If CDAD is suspected or confirmed ongoing, antibiotic use not directed at *C. Difficile* may need to be discontinued.

PRECAUTIONS

- Prescribing polymyxin B in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide a benefit to the patient and increases the risk of the development of drug resistant bacteria.

- 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 which may precipitate respiratory depression. If signs of respiratory paralysis appear, respiration should be assisted as required, and the drug discontinued.
- 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

- Nephrotoxic reactions: Albuminuria, cylinduria, azotemia may occur with use of Polymyxin B for Injection without any increase in dosage.
- Neurotoxic reactions: Facial flushing, dizziness, progressing to ataxia, drowsiness, peripheral paresthesias (circumoral and stocking glove), apnea due to concurrent use of curariform muscle relaxant, other neurotoxic drugs or inadvertent overdose and signs of meningeal irritation with intrathecal administration may occur with use of Polymyxin B for Injection.
- Other 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.