Polymyxin B
for Injection, USP

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

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

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**Polymyxin B**
for Injection, USP

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>Glass Vial</th>
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<tbody>
<tr>
<td>CONCENTRATION</td>
<td>500,000 units per vial</td>
</tr>
<tr>
<td>CLOSURE</td>
<td>20 mm</td>
</tr>
<tr>
<td>UNIT OF SALE</td>
<td>1 vial</td>
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<tr>
<td>BAR CODED</td>
<td>Yes</td>
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</tbody>
</table>

To order, call 1-855-273-0154 or visit www.Athenexpharma.com
POLYMIXIN 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 
  *Escherichia coli*, specifically in meningial infections, *Aerobacter aerogenes*, specifically in bacteremia and *Klebsiella pneumoniae*, specifically in bacteremia, when less potentially toxic drugs are ineffective or contraindicated.

• 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 meningal 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 POLYMIXIN B SULFATE USUALLY SHOW ALBUMINURIA, CELLULAR CASTS, AND AZOTEMIA. DIMINISING 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 POLYMIXIN B SULFATE, PARTICULARLY BACITRACIN, STREPTOMYCIN, NEOMYCIN, KANAMYCIN, GENTAMYCIN, TOBRAMYCIN, AMIKACIN, CEPHALORIDINE, PAROMOMYCIN, VIOMYCIN, AND COLISTIN SHOULD BE AVOIDED.

THE NEUROTOXICITY OF POLYMIXIN 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 curaiform 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 curaiform muscle relaxant, other neurotoxic drugs or inadvertent overdosage 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.