POLYMYXIN B FOR INJECTION USP
500,000 Units
Rx ONLY

To reduce the development of drug-resistant bacteria and maintain the effectiveness of polymyxin B and other antibacterial drugs, polymyxin B should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

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.

RENA! FUNCTION SHOULD BE CAREFULLY DETERMINED AND PATIENTS WITH RENAL DAMAGE AND NITROGEN RETENTION SHOULD HAVE REDUCED DOSAGES. PATIENTS WITH NEPHROTOXICITY DUE TO POLYMYXIN B SULFATE USUALLY SHOW ANOSMIA, CELULAR CASTS, AND AZOTEMIA; DIMINISHING URINE OUTPUT AND ARISING BUN ARE INDICATORS FOR DISCONTINUING TREATMENT WITH THIS DRUG.

NEUROTOXIC REACTIONS MAY BE MANIFESTED BY PLYRURITIS, WEAKNESS, DROWSINESS, ATAXIA, PERIODIC PARESIS, NERVISNESS OF THE EXTREMITIES, AND BLEAKENING 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 SACTRAM, STRIUMYKIN, ARAMONIN, GEMFOLOID, SARCOMYXIN, VICTIMIN, AND COLISTIN SHOULD BE AVOIDED.
C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertonic produc- 
ing strains of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be 
discontinued. Appropriate fluid and electrolyte manage- 
ment, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

PRECAUTIONS

General. Prescribing polymyxin B in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. See WARNING box. 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, su- 
curarine, gallamine, decamethonium and sodium citrate) which may precipitate respiratory depression. If signs of respiratory paralysis appear, respiration should be assisted as required, and the drug discon- 
tinued. As with other antibiotics, use of this drug may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be instituted.

Information for Patients. Patients should be coun- 
selled that antibacterial drugs including polymyxin B should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When polymyxin B is prescribed to treat a bacterial 
infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed.

Dosage and Administration

PARENTERAL

Intraocular. Dissolve 500,000 polymyxin B units in 300 to 500 mL solutions for parenteral dextrose injec- 
tion 5% for continuous drip. 

Adults and children, 15,000 to 25,000 units/kg body weight/day in single or divided doses, may be used for the treatment of Ps aeruginosa infections of the eye, a concentration of 0.1 percent to 0.25 percent (10,000 units to 25,000 units per mL) is administered 
1 to 3 drops every hour, increasing the intervals as response indicates. Subconjunctival injection of up to 100,000 units/day may be used for the treatment of Ps aeruginosa infec- 
tion of the cornea and conjunctiva. Note: Avoid total systemic and intrathecal instillation over 25,000 units/kg/day.

HOW SUPPLIED

Polymyxin B for injection USP: 500,000 polymyxin B units per vial is supplied in rubber-stoppered glass vial with flip off cap, carton of 10. NDC 55390-139-10. 

Storage recommendations

Before reconstitution: Store at 2° to 25°C (36° to 77°F) [See USP Controlled Room Temperature]. Protect from light. Retain in carton until time of use. 

After reconstitution: Product must be stored under refrigeration, between 2° to 8°C (36° to 46°F) and any unused portion should be discarded after 72 hours.

REFERENCES

2. Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Disk Sus- 
3. Clinical Laboratory and Standards Institute (CLSI). Performance Standards for Antimicrobial Suscep- 

Manufactured for Bedford Laboratoriesâ„¢, Bedford, OH 44146 
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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JACQUELINE D COUNCIL
01/27/2012

LILLIE D GOLSON
01/30/2012
for Wm. Peter Rickman