Front

120.00 mm

290.00 mm

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

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Polymyxin B for Injection IP (Lyophilized)

POLYWIN-B
5LAC IU

500000 Units
For Intrathecal / I.M./I.V. Infusion

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 SULPHATE 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 SULPHATE, PARTICULARLY BACITRACIN, STREPTOMYCIN, NEOMYCIN, KANAMYCIN, GENTAMICIN, TOBRAMYCIN, AMIKACIN, CEPHALORIDINE, PAROMOMYCIN, VIOMYCIN, AND COLISTIN SHOULD BE AVOIDED. THE NEUROTOXICITY OF POLYMYXIN B SULPHATE 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.

QUALITATIVE AND QUANTITATIVE COMPOSITION
Active ingredient(s)
Each Vial Contains:
Polymyxin B Sulphate IP
Eq. to Polymyxin B.....500000 Units
Excipients.....q.s.

Excipients with known effect
Not Available.

DOSAGE FORM AND STRENGTH
Lyophilized powder for reconstitution for injection; Polymyxin B 500000 Units.

CLINICAL PARTICULARS
Therapeutic indication
Polymyxin B sulphate is a drug of choice in the treatment of infections of the urinary tract, meninges, and blood stream, caused by susceptible strains of Ps. Aeruginosa. It may also be used as subconjunctival infection 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 the following organisms
1). H. influenzae, specifically meningeal infections
2). Escherichia coli, specifically urinary tract infections
3). Aerobacter aerogenes, specifically bacteremia
4). Klebsiella pneumoniae, specifically bacteremia
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 susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy, In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
Posology and method of administration
Dosing Considerations
Polymyxin B for Injection IP may be administered intravenously, intramuscularly or intrathecally only to hospitalized patients under constant supervision by a physician.
Dosage should not exceed 2.5 mg/kg/day or 200 mg/day. Larger doses may produce nephrotoxicity.
Transient neurotoxic symptoms may be seen with therapeutic doses Estimation of renal function prior to and regularly during therapy is recommended. Monitoring of renal function is strongly recommended in the elderly and in patients with renal impaired function.Safety and efficacy of polymyxin B sulphate in children greater than 2 years is limited. Renal function should be frequently monitored in this population.
Safety and efficacy of intravenous and intramuscular polymyxin B sulphate administration in infants less than 2 years of age is limited. A possibility of higher serum levels and olonged half-life has been reported in infants and neonates, therefore dosage recommendations are not available for this population
Recommended Dose and Dosage Adjustment
Intravenous:
Adults and Children: 15,000 to 25,000 units/kg body weight/day in individuals with normal kidney function. This amount should be reduced from 15,000 units/kg downward for individuals with kidney impairment.
Infusions may be given every 12 hours; however, the total daily dose must not exceed 25,000 units/kg/day.
Infants: Infants with normal kidney function may receive up to 40,000 units/kg/day without adverse effects.
Intramuscular:
Not recommended routinely because of severe pain at injection sites, particularly in infants and children.
Adults and Children: 25,000 to 30,000 units/kg/day. This should be reduced in the presence of renal impairment. The dosage may be divided and given at either 4 or 6 hour intervals.
Infants: Infants with normal kidney function may receive up to 40,000 units/kg/day without adverse effects
Note: Doses as high as 45,000 units/kg/day have been used in limited clinical studies in treating premature and newborn infants for sepsis caused by P. aeruginosa.
Intrathecal:
A treatment of choice for P. aeruginosa meningitis.
Adults and Children over 2 Years of Age: Dosage is 50,000 units once daily intrathecally for 3 to 4 days, then 50,000 units once every other day for at least 2 weeks after cultures of the cerebrospinal fluid are negative and sugar content has returned to normal.
Children under 2 Years of Age: 20,000 units once daily, intrathecally for 3 to 4 days or 25,000 units once every other day. Continue with a dose of 25,000 units once every other day for at least 2 weeks after cultures of the cerebrospinal fluid are negative and sugar content has returned to normal.
Method of administration:
Intravenous Administration: Dissolve 500000 polymyxin B units in 300 to 500 ml solutions for parenteral 5% Dextrose Injection for continuous IV drip. Infusions may be given over a period of approximately 60 to 90 minutes. Reconstituted solution should be stored under refrigeration (2-8°C) and the unused portion should be discarded after 24 hours.
Intramuscular Administration: Dissolve 500000 polymyxin B units in 2 ml Sterile Water for Injection or 0.9% Sodium Chloride Injection. Polymyxin B for Injection IP is compatible with the following reconstitution diluents for intramuscular administration: Sterile Water for Injection, and 0.9% Sodium Chloride Injection.
Intramuscular administration is not recommended routinely because of severe pain at injection sites, particularly in children. Pain may be immediate or delayed. Polymyxin B for Injection IP should be injected well within the body of a relatively large muscle such as in the upper outer quadrant of the buttock or the lateral thigh. To avoid the possibility of radial nerve injury, injections should not be made into the lower and middle thirds of the upper arm. Aspiration and proper anatomical selection of injection site should be observed as a precaution against inadvertent injection into a blood vessel or a major nerve.
Intrathecal Administration: Dissolve 500000 polymyxin B units in 10 ml 0.9% Sodium Chloride Injection IP for 500000 units per ml dosage unit.
In the interest of safety, solutions of parenteral use should be stored under refrigeration (2°-8°C) and any unused portions should be discarded after 24 hours.
Contraindications
it is contraindicated in patients who are hypersensitive to polymyxins, including polymyxin B sulphate, or to any component of the container.
Polymyxin B for Injection IP is contraindicated in patients with myasthenia gravis.
Special warnings and precautions for use
Serious Warnings and Precautions
- Polymyxin B for Injection IP is nephrotoxic therefore renal function should be assessed prior to and regularly during treatment. Dose adjustment is required in patients with reduced renal function.
- Polymyxin B for Injection IP at therapeutic doses may cause serious neurotoxic symptoms as manifested by ataxia, seizure and neuromuscular blockade. These are usually associated with high drug serum levels found in patients with impaired renal function and/or nephrotoxicity
- The concurrent/sequential use of other nephrotoxic drugs including antimicrobials should be avoided with Polymyxin B for Injection IP treatment
- The concurrent/sequential use of anaesthetic and other neurotoxic drugs should be avoided with Polymyxin B for Injection IP treatment. The neurotoxicity of polymyxin B sulphate can result in respiratory paralysis from neuromuscular blockade, especially when the drug is given soon after anaesthesia and/or muscle relaxants. If signs of respiratory paralysis appear, assist respiration and withdraw the drug

General:
The intramuscular, intravenous, and/or intrathecal administration of Polymyxin B for Injection IP should be restricted to hospitalized patients so as to provide constant clinical supervision.
Maximum dosage should not exceed 2.5 mg/kg/day or a total of 200 mg/day in patients with normal renal function.
Intramuscular dosage is not recommended routinely because of severe pain at injection sites. When procaine is used with polymyxin B sulphate to lessen the pain of intramuscular injection, care should be taken not to give; intrathecally or intravenously, solutions that have been prepared with procaine for intramuscular use.
Polymyxin B sulphate should be used with extreme caution in patients with porphyria.
Polymyxin B sulphate is not active and therefore should not be used for the treatment of bacterial infections caused by gram-negative bacteria (Proteus spp., Providencia spp., Morganella spp., Serratia marcescens, Burkholderia spp., Neisseria spp.), all gram-positive bacteria and anaerobes. It is critical that adjunct therapy be initiated immediately if a concomitant bacterial pathogen is documented or suspected.
Cardiovascular
QT Interval Prolongation: The effect of polymyxin B sulphate on prolonged cardiac repolarization, QT interval, and increased risk of developing cardiac arrhythmia and torsades depointes is not known.
Gastrointestinal
Clostridium difficile-associated disease: Clostridium difficult 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.
Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile. C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing 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 management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.
Immune
Hypersensitivity Reactions: Serious hypersensitivity reactions including apnea and bronchoconstriction have been reported in patients receiving polymyxin B sulphate by inhalation administration. Anaphylactoid reactions have been reported with parenteral administration of polymyxin B sulphate. Patients with a known allergy to bacitracin are at higher risk of developing hypersensitivity reactions with the use of polymyxins as cross-reactivity between bacitracin and polymyxins exists.
Before therapy with Polymyxin B for Injection IP is instituted, careful inquiry should be made to determine whether the patient has had a previous hypersensitivity reaction to polymyxins or bacitracin. Polymyxin B for Injection IP should not be administered by inhalation. If an allergic reaction occurs, discontinue the drug. Serious acute hypersensitivity (anaphylaxis or airway constriction) requires emergency treatment as clinically indicated
Neurologic
Neurological disturbances including neuromuscular blockade (generalized muscle weakness, respiratory depression or arrest), seizure, circumoral paresthesia or numbness, vertigo, blurred vision, facial flushing, and slurring of speech, have been reported with polymyxin B sulphate at therapeutic doses. These usually occur with high serum drug concentrations found in patients with renal impairment, drug nephrotoxicity or with inhalation of polymyxin B sulphate.
Mild neurological manifestations of polymyxins usually subside after prompt cessation of polymyxin B sulphate therapy. If signs of respiratory paralysis appear, discontinue use of polymyxin B sulphate and other neurotoxic agents immediately. Apnea should be treated with assisted respiration. Avoid concurrent use of nephrotoxic and/or neuromuscular blocking curariform muscle relaxants and other potential neurotoxic drugs, which may precipitate respiratory depression.
Ophthalmic
Subconjunctival administration of polymyxin B sulphate may be painful. Deep seated or walled off Pseudomonas aeruginosa infections cannot be expected to respond to ophthalmic treatment and may require systemic therapy. Therefore, Polymyxin B for Injection IP should not be used for treatment of these infections.
Renal
Polymyxins induce nephrotoxicity by increasing membrane permeability. Rising blood concentrations of polymyxin B, albuminuria, cellular casts, diminishing urine output and rising BUN have been reported with the use of polymyxin B sulphate at therapeutic doses. Acute renal failure has been reported in patients on polymyxin B sulphate therapy. Nephrotoxicity is dose dependent
Baseline renal function should be assessed prior to and regularly during therapy. Since elderly patients may have impaired renal function, special care should be taken with drug dosing. If renal dysfunction develops, therapy with polymyxin B sulphate should be discontinued immediately. The nephrotoxic effect is usually reversible upon discontinuation of therapy.
In patients with pre-existing renal dysfunction, polymyxin B sulphate dosage adjustment and frequent renal function assessment are required because of the potential for increased drug accumulation under these conditions.
The concurrent use of other nephrotoxic drugs including antimicrobials (particularly bacitracin, aminoglycosides, cephaloridine, cephalothin, amphotericin B, paromycin, polymyxin E (colistin) and vancomycin) should be avoided.
Respiratory
Significant deterioration of lung function including apnea, bronchospasm, decreases in vital capacity, forced expiratory volume over one second and maximum voluntary ventilation have been reported following aerosol administration of polymyxin B sulphate. Polymyxin B for Injection IP should not be administered by inhalation.
Drugs interactions
Overview
Concomitant administration of diuretics and potential nephrotoxic and/or neurotoxic agents including antimicrobials increases the likelihood of renal toxicity, whereas non-polarizing muscle relaxants and other neurotoxic drugs increase the likelihood of serious neurotoxicity.

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Drug-Lab Interactions:
The concurrent use of other nephrotoxic and/or neurotoxic drugs particularly bacitracin, kanamycin, streptomycin, tobramycin, amikacin, cephaloridine, cephalothin, paromycin, polymyxin E (colistin), neomycin, gentamicin, and vancomycin should be avoided.
Due to the effect of polymyxin B sulphate on the release of acetylcholine, non-polarizing muscle relaxants (ether, tubocurarine, gallamine, decamethonium, sodium citrate), depolarizing muscle relaxant succinylcholine, and other neurotoxic drugs should not be used concurrently with polymyxin B sulphate.
The concurrent use of polymyxin B sulphate with potent diuretics such as ethacrynic acid or furosemide should be avoided, since diuretics may enhance polymyxin B sulphate toxicity by altering the antibiotic concentration in serum and tissues.
Drug-Lab Interactions:
Consideration should be given to monitoring electrolyte abnormalities such as hypokalemia, hyponatremia, and hypochloremia.
Drug-Food Interactions:
Information not available.
Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)
Pregnancy
Clinical data from the use of polymyxin B sulphate in pregnant women is not available. Polymyxin B for Injection IP should not be used during pregnancy unless the expected benefit to the mother outweighs any possible risk to the fetus.
Animal studies are also lacking with respect to embryotoxicity and/or teratogenicity of polymyxin B sulphate.
Lactation
It is not known whether polymyxin B sulphate is secreted in breast or animal milk. Because of the potential for unknown effects of the drug in infants being nursed by mothers taking polymyxin B sulphate, a decision should be made to either discontinue nursing or discontinue treatment, taking into account the importance of Polymyxin B for Injection IP drug treatment to the mother and the possible risk to the infant
Paediatric Use
Safety and efficacy of polymyxin B sulphate in children greater than 2 years of age is limited. Renal function should be frequently monitored in this population.
Safety and efficacy of parenteral polymyxin B sulphate in infants less than 2 years of age is limited. A possibility of higher serum levels and prolonged half-life has been reported in infants and neonates, therefore dosage recommendations are not available in this population.
Geriatric Use
Limited data is available on the safety and efficacy of polymyxin B sulphate in the elderly. The decline in renal function with advanced age should be considered and renal function should be assessed prior to and regularly during therapy.
Renal
Patients with impaired renal function demonstrated an increased accumulation of polymyxin B sulphate. Consideration should be given to monitoring renal function (albuminuria, cellular casts, blood urea nitrogen (BUN), serum creatinine or creatinine clearance) prior to and regularly during Polymyxin B for Injection IP treatment.
Effects on ability to drive and use machines
No data available.
Undesirable effects
Adverse Drug Reaction Overview:
The most common drug-related adverse reactions are nephrotoxicity and neurotoxicity, pain at the injection site, urticaria, and electrolyte imbalance.
Clinical Trial Adverse Drug Reactions:
Prospective clinical trials were not conducted for polymyxin B sulphate. Therefore drug-related adverse reactions that could occur are derived from adverse drug reporting from retrospective clinical studies.
Renal and Urinary Disorders: Albuminuria, cylindruria (urinary cast), azotemia (a diminishing urine output and rising BUN).
Nervous System Disorders: Facial flushing, dizziness progressing to ataxia, drowsiness, circumoral, lingual and peripheral paresthesia (stocking-glove distribution), apnea due to concurrent use of curariform muscle relaxants or other neurotoxic drugs, or inadvertent overdosage, signs of meningeal irritation presenting as convulsions and signs of meningismus with intrathecal administration (e.g., fever, headache, seizure, stiff neck and increased cell count and protein in cerebrospinal fluid following intrathecal/intraventricular administration of polymyxin B sulphate).
Immune System Disorders: Urticarial rash at intramuscular injection sites. Allergic hypersensitivity following topical application of polymyxin B sulphate has been reported
General Disorders & Administration Site Conditions: Pain (severe) at intramuscular injection sites, and thrombophlebitis at intravenous injection sites.
General Disorders & Administration Site Conditions: Pain (severe) at intramuscular injection sites, and thrombophlebitis at intravenous injection sites.
Abnormal Hematologic and Clinical Chemistry Findings:
Electrolyte imbalance (including hyponatremia, hypochloremia and hypocalcemia) has been reported during parenteral therapy in patients with serious underlying malignant disease. Eosinophilia has been reported, but the significance of this finding is not established.
Post-Market Adverse Drug Reactions:
Eye Disorder, Ophthalmic application of polymyxin B sulphate has reported low-grade conjunctivitis.
Gastrointestinal Disorders: Pseudomembraneous colitis.
Immune System Disorders: Bronchoconstriction following administration of nebulized polymyxins, anaphylactoid reactions, rash/pruritus, dermatitis and drug fever.
Nervous System Disorders: Facial paralysis, partial deafness, visual disturbance, vertigo, seizure and neuromuscular weakness and neuromuscular blockade.
Renal and Urinary Disorders; Acute renal failure.
Reporting of side effects or suspected adverse reaction
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via
Overdose
Polymyxin-induced toxicity associated with overdose has been reported. Overdose of polymyxin can result in neuromuscular blockade, which can lead to apnea, muscular weakness, vertigo, transient facial paresthesia, slurred speech, vasomotor instability, visual disturbance, confusion, psychosis and possible respiratory arrest. Overdose can also cause renal failure characterized by decreased urine output and increased serum concentrations of BUN and creatinine.
There is no specific antidote for polymyxin B sulphate overdose. In case of polymyxin B sulphate overdose, the drug should be stopped and symptomatic treatment instituted.
Quick diuresis by IV administered mannitol may help to enhance renal clearance of the drug and thus to reduce serum drug levels. Hemodialysis or peritoneal dialysis may help in order to manage renal complications.
PHARMACOLOGICAL PROPERTIES
Mechanism of Action
The antibiotic lipopeptide polymyxin is a large molecular weight detergent. Polymyxin acts by way of three known mechanisms. Polymyxins interact electrostatistically with the outer membranes of gram-negative bacteria and competitively displace divalent cations from the membrane lipids, specifically calcium and magnesium that stabilize the lipopolysaccharide molecule. This disrupts the outer membrane and releases lipopolysaccharides. The change in the permeability of the bacterial membrane leads to leakage of the cell content and subsequently cell lysis and death. Polymyxins The antibiotic lipopeptide polymyxin is a large molecular weight detergent. Polymyxin acts by way of three known mechanisms. Polymyxins interact electrostatistically with the outer membranes of gram-negative bacteria and competitively displace divalent cations from the membrane lipids, specifically calcium and magnesium that stabilize the lipopolysaccharide molecule. This disrupts the outer membrane and releases lipopolysaccharides. The change in the permeability of the bacterial membrane leads to leakage of the cell content and subsequently cell lysis and death. Polymyxins are surface-active amphipathic agents containing both lipophilic and lipophobic groups. They penetrate into cell membranes and interact with phospholipids in the membranes, leading to permeability changes that quickly disrupt cell membranes and cell death. Polymyxins also bind to the lipid A portion of endotoxin or LPS molecules.
Polymyxins are active for gram-negative bacteria only. Acinetobacter spp., Pseudomonas aeruginosa, E coli, Klebsiella spp., Citrobacter spp., Enterobacter spp. (formerly called Aerobacter), Hemophilus influenzae are commonly susceptible to polymyxins. However Proteus spp, Providencia spp, Morganella spp., Serratia spp., Burkholderia spp., Moraxella spp., Neisseria spp., all gram- positive bacteria and most anaerobes are less active/naturally resistant to polymyxins.
Pharmacodynamic properties
Polymyxins are bactericidal targeting the bacterial cell membrane. The pharmacodynamics of polymyxin B sulphate are concentration dependent. The ratio of the area under the plasma concentration-time curve to the bacterial minimum inhibitory concentration (AUC/MIC) is the most predictive efficacy index.
Pharmacokinetic properties
Polymyxin B sulphate is not absorbed from the gastrointestinal tract. Serum polymyxin B sulphate concentrations are low because 79% to 92% of the drug loses its activity due to protein binding. The drug is excreted primarily by the kidneys. Tissue diffusion is poor and the drug does not penetrate well into cerebrospinal fluid, pleural fluid or joints
At therapeutic dosages, polymyxin B sulphate has been reported to cause nephrotoxicity as shown by slight tubular damage.
Following a 50 mg intramuscular dose, a peak concentration of 8 µg/ml was achieved in approximately 2 hours and serum half-life was approximately 6 hours. Following multiple 2-4 mg/kg/day intramuscular polymyxin B sulphate, in divided doses, blood serum levels were reported to be 1-8 µg/ml. The peak levels occurred within 30 minutes to 2 hours after injection, the half-life was about 4.5 to 6 hours and the drug remained detected up to 12 hours. When Polymyxin B sulphate was given at a dose of 2.5 mg/kg/day for 7 days, drug accumulation was reported and peak serum concentrations reached 15-30 µg/ml..
The primary route of polymyxin B sulphate excretion is via the kidney. After an initial dose of polymyxin B sulphate there was a 12 to 24 hour lag period with only a small amount of drug (<1%) being recovered in the first 12 hours after injection. As therapy continues, the urinary concentration increases and eventually 60% of the dose can be accounted for in the urine and urinary concentrations of 10 to 100 µg/ml are attained. The fate of the remaining 40% was unclear, as polymyxins are not excreted in bile.
Polymyxins are not effectively removed by hemodialysis and the effect of high-flux dialyzers is unknown. No information concerning the removal of polymyxin B sulphate by peritoneal dialysis is available.
NONCLINICAL PROPERTIES
Animal Toxicology and/or Pharmacology
Carcinogenesis
Long-term studies in animals to evaluate carcinogenic potential have not been conducted with polymyxin B sulphate.
Mutagenesis
Studies to evaluate mutagenic potential have not been conducted with polymyxin B sulphate.
Impairment of Fertility
DESCRIPTION
Polymyxin B for Injection (polymyxin b sulphate) is one of a group of basic polypeptide antibiotics derived from B polymyxa (Baerosporous). Polymyxin B polymyxin b sulphate) sulphate is the sulphate salt of Polymyxins B, and B,, which are produced by the growth of Bacillus polymyxa (Prazmowski) Migula (Fam. Bacillacea). It has a potency of not less than 6000 polymyxin B (polymyxin b sulphate) units per mg, calculated on the anhydrous basis The structural formulae are;
PHARMACEUTICAL PARTICULARS
Incompatibilities
This medicinal product must not be mixed with other medicinal products.
Polymyxin B, ($R=CH_2$)
Polymyxin B2 (R=H)
From a microbiological point of view, once opened, the product should be used immediately. If not used immediately.
NOTE: Parenteral drug products should be inspected visually for particulate matter before administration.
Shelf-life
Refer actual product label.
Packaging information
Amber colour glass vial sealed with flip off seal.
Storage and handling instructions
Storage: Store protected from light, at a temperature between 20°C to 25°C.
Reconstituted solutions should be stored under refrigeration (2-8°C) and the unused portion should be discarded after 24 hours.
List of excipients
Not Applicable.
PATIENT COUNSELING INFORMATION
Polymyxin B for Injection IP will be administered by a health care professional in a hospital or under direct supervision and monitoring by a healthcare professional. Although it is common to feel better early in the course of therapy, the medication should be used exactly as directed.

Marketed by:

windlas
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