have kidney problems
·Avoid use of other drugs that may be harmful to kidneys such as some antibiotics
·Avoid using anesthetics and muscle relaxants at the same time as polymyxin B sulphate as this can slow and stop breathing.

SIDE EFFECTS

The most common side effects are kidney problems such as albuminuria, cellular casts, diminishing urine output and rising BUN, neurological problems such as apnea, numbness, vertigo, blurred vision, facial flushing, and slurring of speech, pain at the injection site, skin redness and itching.
A hypersensitivity (allergic, anaphylactic) reaction with symptoms such as bronchoconstriction (narrowing of the breathing tubes) and interruption in breathing (apnea), rash, hives, itching, and swelling of tissues have been reported with inhaled polymyxin B sulphate.

Caution : It is to be given to patient hospitalized so as to provide contstant supervision by a Physician.

Adverse Drug Reaction

The most common drug-related adverse reactions are nephrotoxicity and neurotoxicity, pain at the injection site, urticaria, and electrolyte imbalance.

This is not a complete list of side effects. For any unexpected effects while taking Polymyxin B for Injection IP, contact your doctor or pharmacist.

STORAGE:

Store protected from light & moisture at a temperature between 20°C to 25°C.
Improper storage may deteriorate the product.

DOSAGE AND ADMINISTRATION

Parenteral:
Intravenous: Dissolve 500,000 polymyxin B (polymyxin b sulfate) units in 300 to 500 mL solutions for parenteral dextrose injection 5% for continuous drip.
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. Dissolve 500,000 polymyxin B units in 2 mL sterile water for injection or sodium chloride injection or procaine hydrochloride injection 1%.
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 prematures and newborn infants for sepsis caused by *Ps aeruginosa.*
Intrathecal: A treatment of choice for *Ps aeruginosa*meningitis. Dissolve 500,000 polymyxin B (polymyxin b sulfate) units in 10 mL sodium chloride injection IP for 50,000 units per mL dosage unit.
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.
IN THE INTEREST OF SAFETY, SOLUTIONS OF PARENTERAL USE SHOULD BE STORED UNDER REFRIGERATION, AND ANY UNUSED PORTIONS SHOULD BE DISCARDED AFTER 72 HOURS.

Topical:

Ophthalmic: Dissolve 500,000 polymyxin B (polymyxin b sulfate) units in 20 to 50 mL sterile water for injection or sodium chloride injection IP for a 10,000 to 25,000 units per mL concentration.

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*infections of the cornea and conjunctiva.

Note: *Avoid total systemic and ophthalmic instillation over 25,000 units/kg/day.*

DOSAGE: As directed by physician. Unused portion must be discarded.
PRESENTATION : A white dry powder filled in 5 ml amber colour glass vial.

Manufactured by : **Pacebiotech Pharma(India) Pvt.Ltd.**
(A WHO-GMP Compliance Unit)
Nahan Road Village Surajpur P.O. Puruwala
Tehsil Paonta Sahib, District Sirmaur-173025(H.P.)

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"Scan for batch certificate"

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

℞ Polymyxin B for Injection IP

AMERICAN
Polycan B 5L IU 500000 IU
Injection

FOR IM/IV INTRATHECAL USE ONLY

Composition :
Each Vial contains ;
Polymyxin B Sulphate IP (Sterile)
Eq. to Polymyxin B 500000 IU

Description:

Polymyxin B is a group of basic polypeptides antibiotics derived from B Polymyxa(B Aerospourous). It is a sulphate salt of polymyxin B1 & B2 which are produced by the growth of bacillius polymyxa. It has a potency of not less than 6000 units per mg calculated on anhydrous basis. Each vial contain 500000 units

CLINICAL PHARMACOLOGY

Polymyxin B sulfate has a bactericidal action against almost all gram-negative bacilli except the *Proteus* group. Polymyxins increase the permeability of the bacterial cell membrane leading to death of the cell. All gram-positive bacteria, fungi, and the gram-negative cocci are resistant to polymyxin B. Appropriate methods should be used when performing *in vitro* susceptibility testing of polymyxin B. Polymyxin B sulphate is not absorbed from the normal alimentary tract. Since the drug loses 50 percent of its activity in the presence of serum, active blood levels are low. Repeated injections may give a cumulative effect. Levels tend to be higher in infants and children. The drug is excreted slowly by the kidneys. Tissue diffusion is poor and the drug does not pass the blood brain barrier into the cerebrospinal fluid. In therapeutic dosage, polymyxin B sulfate causes some nephrotoxicity with tubule damage to a slight degree.Polymyxins are bactericidal targeting the bacterial cell membrane..

When it should not be used:

Polymyxin B for Injection IP should not be used if:
You have or have had an allergic reaction to polymyxin B or other polymyxin
You have myasthenia gravis

Consult your doctor before taking medicine in following:

You have a kidney disease.
Are pregnant or planning to get pregnant.
You are taking any prescription medications, over the counter medications or herbal/natural products or remedies.
You have a prior allergy to a medication.
You have porphyria (disease of pigment metabolism to the body).
·If you develop severe or persistent diarrhoea, this may be a sign of a more serious condition and you should contact a doctor immediately.

Acute Infections Caused by Susceptible Strains of Pseudomonas aeruginosa.

Polymyxin B sulphate 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 susceptiblestrains of the following organisms, when lesspotentially toxic drugs are ineffective or contraindicated:
H influenzae, specifically meningeal infections.
Escherichia coli, specifically urinary tract infections.
Aerobacteraerogenes, specifically bacteraemia.
Klebsiellapneumoniae, specifically bacteremia.

NOTE: IN MENINGEAL INFECTIONS, POLYMYXINB SULFATE SHOULD BE ADMINISTERED ONLY BY THE INTRATHECAL ROUTE.

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 orstrongly 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.

CONTRAINDICATIONS

This drug is contraindicated in persons with a prior history of hypersensitivity reactions to polymyxins. Polymyxin B is contraindicated in patients with myasthenia gravis.

WARNINGS

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Polymyxin B for Injection . Polymyxin B for Injection may range in severity from mild diarrhoea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile.*
·**Polymyxin B** can be harmful to the kidney, so your doctor will determine whether this drug is suitable for you if you have kidney problems
·**Polymyxin B** can be harmful to the brain and nervous system and may cause seizures, movement coordination problems (e.g. ataxia) especially in those with kidney problems, so tell your doctor if you