



Consumer/Patient Information Leaflet

Brand Name: POLYMxB
Polymyxin B for Injection USP (Lyophilized)
For Intravenous/Intramuscular/Intrathecal dosage only

What's in your injectable medicine?

The name of medicine is **POLYMxB** (Containing Polymyxin B Sulphate USP Lyophilized as an active ingredient). It contains the active ingredient of **5, 00,000 Units** in each vial of **POLYMxB**.

PolymxB is a white or almost white cake/powder which on reconstitution gives clear colourless liquid.

(Kindly refer to Pack insert for more pharmacological / usage details)

What is Polymyxin B sulphate?

Polymyxin B Sulfate is one of a group of basic polypeptide antibiotics derived from *B. polymyxa* (*B. aerosporus*). Polymyxin B sulfate is the sulfate salt of Polymyxins B1 and B2, which are produced by the growth of *Bacillus polymyxa* (Prazmowski) Migula (Fam. Bacillacea).

How does it work?

Polymyxin B sulfate has a bactericidal action against almost all gram-negative bacilli except the *Proteus* group. Polymyxins increase the permeability of bacterial cell wall membranes. All gram-positive bacteria, fungi, and the gram-negative cocci, *N. gonorrhoeae* and *N. meningitidis*, are resistant.

What should I tell my health care provider/ Physician before I take this medicine?

They need to know if you have any of these conditions:

- kidney disease
- lung disease
- myasthenia gravis or other neuromuscular disease



- an unusual or allergic reaction to polymyxin B, other antibiotics, other medicines, foods, dyes or preservatives
- pregnant or trying to get pregnant
- breast-feeding

If you are given more dose of POLYMxB than you have?

Polymyxin overdose resulted in acute renal failure and various manifestations of neurotoxicity, including neuromuscular blockade and apnea. It should be emphasized that cases of Polymyxin overdose with fatal consequences are scarce . There is no antidote for Polymyxin overdose. Management requires early cessation of the medication and appropriate supportive treatment. In the presence of established acute renal failure, haemodialysis and peritoneal dialysis can only manage renal complications, since they have little influence on the elimination of polymyxins, as discussed above. If apnea occurs, mechanical ventilation support is needed.

What are the special precautions for use of POLYMxB?

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, succinylcholine, 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 discontinued. 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

Warning:

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.

Patients with nephrotoxicity due to POLY-MxB 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, peripheral 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 neurotoxicity of POLY-MxB can result in respiratory paralysis from neuromuscular blockade, especially when the drug is given soon after anesthesia and / or muscle relaxants

How will POLYMxB be given to you?

POLYMxB is administered by Intrathecal / Intramuscular/ Intravenous Infusion

Intravenous :

Dissolve 5, 00,000 Units Polymyxin B Sulfate in 300 to 500 ml of 5% dextrose in water for continuous intravenous drip.

Intramuscular:

Dissolve 5, 00,000 Units Polymyxin B Sulfate in 2ml sterile distilled water (Sterile Water for Injection U.S.P.) or sterile physiologic saline (Sodium Chloride Injection U.S.P.) or 1% procaine hydrochloride solution.

Intrathecal :

A treatment of choice for *Ps. aeruginosa* meningitis.

Dissolve 5,00,000 Units Polymyxin B Sulfate in 5ml of sterile physiologic saline (Sodium Chloride Injection U.S.P.) for 50,000 units per ml dosage unit.

IN THE INTEREST OF SAFETY, SOLUTIONS FOR PARENTERAL USE SHOULD BE STORED UNDER REFRIGERATION AND ANY UNUSED PORTION SHOULD BE DISCARDED AFTER 72 HOURS.



How to store the Medicine?

Vials of POLYMxB should be stored in a cool and dry place.
Keep out of the reach of children.

The product license/ authorization holder is:

BHARAT SERUMS AND VACCINES LIMITED

Plot no K-27, Jambivili village, Anand Nagar, Additional M.I.D.C,
Ambernath (East) Maharashtra State

Manufactured in India by:



BHARAT SERUMS AND VACCINES LIMITED

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