DESCRIPTION: Neomycin and Polymyxin B Sulfates Solution for Irrigation is a concentrated antibiotic solution intended for irrigation of the intact urinary bladder. Neomycin and Polymyxin B Sulfates Solution for Irrigation is for irrigation of the urinary bladder only, and is not to be used for systemic administration.

Neomycin sulfate, an antibiotic of the aminoglycoside group, is the salt of sulfamic acid and N-acetylprocainamide. It has a potency equivalent to not less than 600 µg of neomycin per mg. The structural formulae are:

\[
\text{Neomycin B (R1 = H, R2 = CH2NH2)}
\]

\[
\text{Neomycin C (R1 = CH2NH2, R2 = H)}
\]

Polymyxin B sulfate, a polypeptide antibiotic, is the salt of polymyxin B2 and B3 produced by the growth of Bacillus polymyxa. It has a potency of not less than 6000 units per mg. The structural formulae are:

\[
\text{Polymyxin B (H2NCH2)2O3SO4}
\]

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\]

CLINICAL PHARMACOLOGY: After prophylactic irrigation of the intact urinary bladder, neomycin and polymyxin B are absorbed in clinically insignificant quantities. A neomycin serum level of 0.1 µg/mL has been observed with a neomycin-containing irrigation solution. This level is well below that which has been associated with systemic toxicity. Neomycin-induced toxicity is rarely irritating.

Microbiology: The prepared Neomycin and Polymyxin B Sulfates Solution for Irrigation is bactericidal. The aminoglycosides act by inhibiting normal protein synthesis in susceptible microorganisms. Polymyxins increase the permeability of bacterial cell wall membranes. The solution is active in vitro against:

- Escherichia coli
- Staphylococcus aureus
- Hemophilus species
- Klebsiella and Enterobacter species
- Neisseria species, and
- Pseudomonas aeruginosa.

It is not active in vitro against Serratia marcescens and streptococci.

Bacterial resistance may develop following the use of the antibiotic in the catheter-rinse solution.

INDICATIONS AND USAGE: Neomycin and Polymyxin B Sulfates Solution for Irrigation is indicated for the prophylaxis of urinary tract infection associated with indwelling catheters. Neomycin and Polymyxin B Sulfates Solution for Irrigation is indicated for irrigation of the intact urinary bladder in patients with indwelling catheters to prevent or treat ascending urinary tract infection. When applied topically, it is not systemic.

WARNINGS: PROPHYLACTIC BLADDER CARE WITH NEOMYCIN AND POLYMYPXIN B SULFATE SOLUTION FOR IRRIGATION SHOULD NOT BE GIVEN WHERE THERE IS A POSSIBILITY OF SYSTEMIC ABSORPTION. Neomycin and Polymyxin B Sulfates Solution for Irrigation should not be used for any condition in which absorption may be hazardous. Neomycin and Polymyxin B Sulfates Solution for Irrigation should not be used for IRRIGATION OTHER THAN FOR THE URINARY BLADDER. Systemic absorption should be avoided in patients with defects in the bladder mucosa or bladder fistula, as well as in association with operative procedures on the bladder wall, because of the risk of toxicity due to systemic absorption following diffusion to absorptive tissues. When absorbed, neomycin and polymyxin B are nephrotoxic and antibiotics, and the neutrophilic potential of polymyxin B. In addition, when absorbed, are neurotoxins: neomycin can destroy fibers of the acoustic nerve causing permanent bilateral deafness; neomycin and polymyxin B are additive in their neuromuscular blocking effects, not only in terms of potency and duration, but also in terms of characteristics of the blocks produced.

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