

Aminoglycosides, when absorbed, can cause fetal harm when administered to a pregnant woman. Aminoglycoside antibiotics cross the placenta and there have been several reports of total, irreversible, bilateral, congenital deafness in children whose mothers received streptomycin during pregnancy. Although serious side effects have not been reported in the treatment of pregnant women with other aminoglycosides, the potential for harm exists. If NEOSPORIN G.U. Irrigant Sterile is used during pregnancy, the patient should be apprised of the potential hazard to the fetus (see **PRECAUTIONS**).

PRECAUTIONS:

General: Ototoxicity, nephrotoxicity, and neuromuscular blockade may occur if NEOSPORIN G.U. Irrigant ingredients are systemically absorbed (see **WARNINGS**). Absorption of neomycin from the denuded bladder surface has been reported. Patients with impaired renal function, infants, dehydrated patients, elderly patients, and patients receiving high doses of prolonged treatment are especially at risk for the development of toxicity.

Irrigation of the bladder with NEOSPORIN G.U. Irrigant may result in overgrowth of nonsusceptible organisms, including fungi. Appropriate measures should be taken if this occurs. The safety and effectiveness of the preparation for use in the care of patients with recent lower urinary tract surgery have not been established.

Urine specimens should be collected during prophylactic bladder care for urinalysis, culture, and susceptibility testing. Positive cultures suggest the presence of organisms which are resistant to the bladder rinse antibiotics.

Pregnancy: Teratogenic Effects: Pregnancy Category D. See **WARNINGS** section.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS: Neomycin occasionally causes skin sensitization when applied topically; however, topical application to mucus membranes rarely results in local or systemic hypersensitivity reactions.

Irritation of the urinary bladder mucosa has been reported.

Signs of ototoxicity and nephrotoxicity have been reported following parenteral use of these drugs and following the oral and topical use of neomycin (see **WARNINGS**).

DOSAGE AND ADMINISTRATION: This preparation is specifically designed for use with "three-way" catheters or with other catheter systems permitting **continuous** irrigation of the urinary bladder. The usual irrigation dose is one 1-mL ampul a day for up to 10 days.

Using strict aseptic techniques, the contents of one 1-mL ampul of NEOSPORIN G.U. Irrigant Sterile (neomycin sulfate-polymyxin B sulfate solution for irrigation) should be added to a 1,000-mL container of isotonic saline solution. This container should then be connected to the inflow lumen of the "three-way" catheter which has been inserted with full aseptic precautions; use of a sterile lubricant is recommended during insertion of the catheter. The outflow lumen should be connected, via a sterile disposable plastic tube, to a disposable plastic collection bag. Stringent procedures, such as taping the inflow and outflow junction at the catheter, should be observed when necessary to insure the junctional integrity of the system.

For most patients, the inflow rate of the 1,000-mL saline solution of neomycin and polymyxin B should be adjusted to a slow drip to deliver about 1,000 mL every 24 hours. If the patient's urine output exceeds 2 liters per day, it is recommended that the inflow rate be adjusted to deliver 2,000 mL of the solution in a 24-hour period.

It is important that the rinse of the bladder be **continuous**; the inflow or rinse solution should not be interrupted for more than a few minutes.

Preparation of the irrigation solution should be performed with strict aseptic techniques. The prepared solution should be stored at 4°C, and should be used within 48 hours following preparation to reduce the risk of contamination with resistant microorganisms.

HOW SUPPLIED: 1-mL ampuls, boxes of 10 (61570-047-10) and 50 ampuls (61570-047-50); 20-mL multi-dose vial (NDC 61570-048-20).

Store at 2° to 8°C (36° to 46°F).

RX ONLY.

Prescribing Information as of May 2003.



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