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ADVERSE REACTIONS

Cell Death: Mitomycin is cytotoxic. Use of mitomycin in concentrations higher than 0.2 mg/ml or for longer than 2 minutes may lead to uncontrolled corneal and/or scleral damage including thinning or perforation. Direct contact with the eye should be avoided. Complete damage may result in cell death. (5.1)

Hypotony: The use of mitomycin has been associated with an increased incidence of post-operative hypotony. (5.2)

Cataract Development: Use in phakic patients has been correlated to a higher incidence of lens opacification and cataract formation. (5.3)

Embryo-Fetal Toxicity: Can cause fetal harm. Advise of potential risk to a fetus. Verify pregnancy status in females of reproductive potential prior to use. (5.4, 5.6, 8.3)

WARRANTINGS AND PRECAUTIONS

Stability: Lyophilized MITOSOL® (0.05 and 0.15 mg/mL) is stable for at least 3 months at room temperature. Lyophilized MITOSOL® (0.2 mg/mL) is stable for at least 1 month at room temperature. Lyophilized MITOSOL® (0.6 mg/mL) is stable for at least 1 month at room temperature. Lyophilized MITOSOL® (1 mg/mL) is stable for at least 1 month at room temperature. Lyophilized MITOSOL® (2 mg/mL) is stable for at least 1 month at room temperature. Lyophilized MITOSOL® (5 mg/mL) is stable for at least 1 month at room temperature. Lyophilized MITOSOL® (10 mg/mL) is stable for at least 1 month at room temperature. Lyophilized MITOSOL® (20 mg/mL) is stable for at least 1 month at room temperature. Lyophilized MITOSOL® (50 mg/mL) is stable for at least 1 month at room temperature. Lyophilized MITOSOL® (100 mg/mL) is stable for at least 1 month at room temperature.

To report SUSPECTED ADVERSE REACTIONS, contact Mobius Laboratories at 1-844-6486 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION

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Mitosol®
(mitomycin for solution)
0.2 mg/vial
Kit for Ophthalmic Use

1. Getting Started
Non-Sterile Circulating Nurse:
- Open outer pack. Affix sterile transfer of all contents to sterile field.
- Sterile Surgical Technician:
  - Open sterile inner tray.

2. Reconstituting Mitosol®
- a. Remove vial and vial adapter from blue foam pouch.
- b. Screw white plunger rod to rubber plunger of pre-filled syringe (Fig. 1).
- c. Press firmly and screw the blue end of vial adapter into the blue end of the syringe connector (Fig. 2).

NOTE: Do not force plunger. Syringe will not operate if vial adapter and syringe connector are not properly connected. Forcing plunger may result in syringe leakage and Mitosol® exposure.

3. Preparing sponges
- a. Invert vial and syringe and draw full volume of medication into syringe (Fig. 5).
- b. Remove all sponges from sponge tray.
- c. Return to sponge tray only those sponges to be saturated with Mitosol®.

h. Mitosol® must be used within 1 hour of reconstitution:
- Inject medication into sponge container.
- Saturating sponges
- Reconstituted Mitosol® should remain undisturbed in sponge container for 30 seconds (Fig. 7).
- Do not force syringe plunger. See note at step 2.
- If any excess fluid remains, withdraw plunger of TB syringe, drawing excess fluid into syringe.

4. Using Mitosol®
- a. With both syringes connected, the TB syringe to one end, the pre-filled syringe to the other, open sponge container, offering contents to surgeon for placement on surgical site (Fig. 8).
- b. Apply saturated sponges to surgical site for two minutes. Remove sponges from eyes and copiously irrigate surgical site.
- c. As used sponges are removed from surgical site, accept unused sponges back into sponge container for disposal. Close container lid.
- d. With syringes still connected to sponge container, remove entire assembly from surgical field in chemotherapy waste disposal bag.

b. Unscrew the syringe with safety connector from vial and vial adapter. (Fig. 6)
  - Note: DO NOT remove safety connector from syringe.
  - Place vial and vial adapter in chemotherapy waste disposable bag (yellow bag), and set bag aside, within sterile field, for additional use.
  - Take sponge container from sterile inner tray.
  - Screw both syringes into sponge container, the TB syringe to one end, the reconstituted Mitosol® to the other.

Storage
- Store at 20°C to 25°C (68°F to 77°F), Avoid excessive heat. Protect from light.

Handling Procedures
- Mitosol® is a cytotoxic drug. Procedures for Proper Handling and Disposal of anti-cancer drugs should be followed. Appropriate containment and disposal devices are included within the Mitosol® (mitomycin for solution) Kit for Ophthalmic Use.

17. PATIENT COUNSELING INFORMATION
- Instruct patients to discuss with their physician if they are pregnant or if they might become pregnant (see Use in Specific Populations [8.1]).
- Instruct patients to discuss with their physician if they have demonstrated a hypersensitivity to mitomycin in the past (see Contraindications [4.1]).

13. NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Adequate long-term studies in animals to evaluate carcinogenic potential have not been conducted with Mitosol®. Intravenous administration of mitomycin has been found to be carcinogenic in rats and mice. At doses approximating the recommended clinical injectable doses in humans, mitomycin produces a greater than 100 percent increase in tumor incidence in male Sprague-Dawley rats, and a greater than 50 percent increase in tumor incidence in female Swiss mice. The effect of Mitosol® on fertility is unknown.