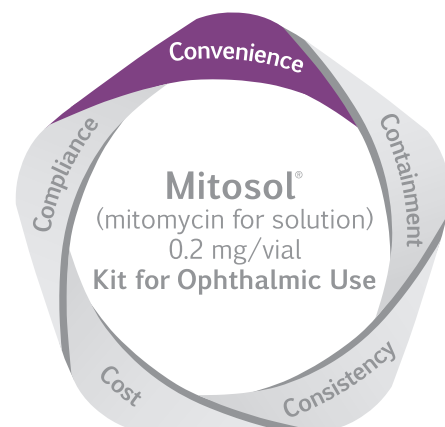


10 Ways Mitosol® Defines Convenience

1. Includes a sterile procedural kit to reconstitute mitomycin C (MMC) at the time of use.
2. Extended 2-year shelf life.
3. Turnkey system: preparation, use, delivery, and disposal.
4. Room temperature storage - No refrigeration.
5. Requires no light-shielding.
6. Requires no advance prescription.
7. Eliminates case cancellations or rescheduling due to outdated or absent MMC.
8. Pre-cut sponges speed preparation & eliminate scissor cut fragments.
9. Reduces OR, staff, & physician downtime.
10. Eliminates rushed preparation for last-minute cases.

Mitosol®: Ready-when-you-are convenience when handling MMC.



Mitosol® Facts

FDA-Approved for Ophthalmology	✓
Assured Sterility, Potency, Dosing	✓
AORN Compliant Sterile Transfer	✓
Closed Fluid Transfer	✓
Room Temp Storage	✓
cGMP Manufacturing Controls	✓
Detailed Instructions for Use	✓
NIOSH Compliant Disposal	✓
No "Black Box Warning"	✓
Shelf Life up to 24 months	✓



INDICATION

Mitosol® (mitomycin for solution) 0.2 mg/vial Kit for Ophthalmic Use is an antimetabolite indicated as an adjunct to ab externo glaucoma surgery.

Dosage & Administration

Mitosol® is intended for topical application to the surgical site of glaucoma filtration surgery and must be reconstituted prior to application. Sponges provided within the Mitosol® kit should be fully saturated with the entire reconstituted contents in a manner prescribed in the Instructions For Use. The sponge(s) should be applied to the treatment area for two minutes. Reconstituted Mitosol® should be used within one hour of reconstitution.

IMPORTANT SAFETY INFORMATION

Contraindications

Mitosol® is contraindicated in patients that have demonstrated

a hypersensitivity to mitomycin and in women who are or may become pregnant during therapy.

Warnings & Precautions

Cell Death, mitomycin is cytotoxic. Use of mitomycin in concentrations higher than 0.2mg/mL or use for longer than 2 minutes may lead to unintended corneal and/or sclera damage including thinning or perforation. Direct contact with the corneal endothelium will result in cell death.

Hypotony. The use of mitomycin has been associated with an increased instance of post-operative hypotony.

Cataract Development. Use in phakic patients has been correlated to higher instance of lenticular change and cataract formation.

Adverse Events & Reactions

The most frequent adverse reactions to Mitosol® occur locally and include hypotony, hypotony maculopathy, blebitis, endophthalmitis, vascular reactions, corneal reactions, and cataract.

