

How to Bill MITOSOL®

J7315 Mitomycin, ophthalmic, 0.2 mg
APC – 01448 - APC Descriptor – Ophthalmic mitomycin - Status Indicator - G

Mitosol has pass-through status in the OPPS and ASC and is separately payable as of April 1, 2013.

April 2013 Update of the Ambulatory Surgical Center (ASC) Payment System [MM8237](#)

April 2013 Update of the Hospital Outpatient Prospective System (OPPS) [MM8228](#)

Mitosol Indication ([Full prescribing information](#))

MITOSOL® is an anti-metabolite indicated for use as an adjunct to ab externo glaucoma surgery.

Diagnosis Code(s) for Ab Externo Glaucoma Surgery

Enter the appropriate ICD-9-CM code for MITOSOL® on the appropriate claim line of the form.

| | | | |
|--------|----------------------------------|--------|---------------------------------------|
| 365.10 | Open-angle glaucoma, unspecified | 365.13 | Pigmentary glaucoma |
| 365.11 | Primary open angle glaucoma | 365.15 | Residual stage of open angle glaucoma |
| 365.12 | Low tension glaucoma | | |

Procedure Code

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NOTE: MITOSOL® is for topical application.

Drug Name, NDC, Quantity and Charge

Note the full name of the drug administered including strength, the NDC and the number of unit(s) on the appropriate claim lines:

| NDC | Drug Name | Unit(s) | Direct Price/ASP |
|-------------|---|---------|--------------------|
| 49771-02-01 | Mitosol® (mitomycin for solution) 0.2 mg/vial Kit for Ophthalmic Use | One (1) | \$359.00 per 1 kit |

Please note: ASP (Average Sales Price), WAC (Wholesale Acquisition Cost) and AWP (Average Wholesale Price) based pricing is only to be used to determine the cost of the drug and does not include an administration charge. **Always** check with payor regarding correct claim details if you have any questions. The content of this communication does not constitute a professional service. Always consult with the appropriate payor or a competent reimbursement professional for interpretation and recommendations and other matters specific to your situation.

THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

Mitosol® (mitomycin for solution)**Kit for Ophthalmic Use****Rx only****BRIEF SUMMARY: Please consult package insert for full prescribing information**

INDICATIONS AND USAGE: Mitosol® is an antimetabolite indicated for use as an adjunct to ab externo glaucoma surgery.

CONTRAINDICATIONS: Hypersensitivity: Mitosol® is contraindicated in patients that have demonstrated a hypersensitivity to mitomycin in the past. **Pregnant women:** Mitosol® may cause fetal harm when administered to a pregnant woman. Mitomycin administered parenterally has been shown to be teratogenic in mice and rats when given at doses equivalent to the usual human intravenous dose. Mitosol® is contraindicated in women who are or may become pregnant during therapy. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

WARNINGS AND PRECAUTIONS: Cell Death: Mitomycin is cytotoxic. Use of mitomycin in concentrations higher than 0.2 mg/mL or use for longer than 2 minutes may lead to unintended corneal and/or scleral 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 Formation:** Use in phakic patients has been correlated to a higher instance of lenticular change and cataract formation.

ADVERSE REACTIONS: Ophthalmic Adverse Reactions: The most frequent adverse reactions to Mitosol® occur locally, as an extension of the pharmacological activity of the drug. These reactions include: *Blebitis*: bleb ulceration, chronic bleb leak, encapsulated/cystic bleb, bleb-related infection, wound dehiscence, conjunctival necrosis, thin-walled bleb; *Cornea*: corneal endothelial damage, epithelial defect, anterior synechiae, superficial punctate keratitis, Descemet's detachment, induced astigmatism; *Endophthalmitis*; *Hypotony*: choroidal reactions (choroidal detachment, choroidal effusion, serous choroidal detachment, suprachoroidal hemorrhage, hypotony maculopathy, presence of supraciliochoroidal fluid, hypoechogenic suprachoroidal effusion); *Inflammation*: iritis, fibrin reaction; *Lens*: cataract development, cataract progression, capsule opacification, capsular constriction and/or capsulotomy rupture, posterior synechiae; *Retina*: retinal pigment epithelial tear, retinal detachment (serous and rhegmatogenous); *Scleritis*: wound dehiscence; *Vascular*: hyphema, central retinal vein occlusion, hemiretinal vein occlusion, retinal hemorrhage, vitreal hemorrhage and blood clot, subconjunctival hemorrhage, disk hemorrhage; *Additional Reactions*: macular edema, sclera thinning or ulceration, intraocular lens capture, disk swelling, malignant glaucoma, lacrimal drainage system obstruction, ciliary block, corneal vascularization, visual acuity decrease, cystic conjunctival degeneration, upper eyelid retraction, dislocated implants, severe loss of vision.

USE IN SPECIFIC POPULATIONS: Pregnancy: Teratogenic Effects: Pregnancy Category X (*see Contraindications*). **Nursing Mother:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from Mitosol®, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. It is recommended that women receiving Mitosol® not breast feed because of the potential for serious adverse reactions in nursing infants. **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established. **Geriatric Use:** No overall differences in safety and effectiveness have been observed between elderly and younger patients.

More detailed information is available upon request.

For information about Mitosol® contact: 1-877-EYE-MITO (1-877-393-6486)

Please also see full Prescribing Information at MobiusTherapeutics.com

Manufactured for:

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