PRESCRIBING INFORMATION

Pr MIOSTAT*

Carbachol Intraocular Solution, USP

0.01% w/v

Parasympathomimetic

Sterile

Alcon Canada Inc.
2665 Meadowpine Blvd
Mississauga, ON L5N 8C7
www.alcon.ca

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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Intraocular injection	Intraocular Solution / Carbachol 0.01% w/v	None. *For a complete listing see Dosage Forms, Composition and Packaging section.*

INDICATIONS AND CLINICAL USE

MIOSTAT* (Carbachol Intraocular Solution, USP) is indicated for:

- Intraocular use for obtaining miosis during surgery
- Reduction of the intensity of intraocular pressure elevation in the first 24 hours after cataract surgery

Pediatrics (< 18 years of age):
The safety and effectiveness of MIOSTAT* have not been established in pediatric patients.

CONTRAINDICATIONS

Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the Dosage Forms, Composition and Packaging section of the prescribing information.

WARNINGS AND PRECAUTIONS

General
For single-dose intraocular use only. Discard unused portion.

MIOSTAT* should be used with caution in patients with acute cardiac failure, bronchial asthma, peptic ulcer, hyperthyroidism, gastrointestinal spasm, urinary tract obstruction and Parkinson's disease.

The use of MIOSTAT* may increase surgically induced intraocular inflammation.

The vial stopper contains natural rubber (latex), which may cause severe allergic reactions.

Carcinogenesis and Mutagenesis
Studies in animals to evaluate the carcinogenic potential have not been conducted.

Driving and Using Machinery
Miosis may cause blurred vision and difficulty in dark adaptation. If temporary blurred vision occurs following surgery where MIOSTAT* was used, the patient must wait until vision clears before driving or using machinery.

Special Populations
Pregnant Women: There are no adequate and well-controlled studies in pregnant women. MIOSTAT* should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Women: It is not known if carbachol is excreted in breast milk. Exercise caution when administering MIOSTAT* to a nursing woman.

Pediatrics (<18 years of age): The safety and effectiveness of MIOSTAT* in pediatric patients have not been established.

ADVERSE REACTIONS

Adverse reactions that have been reported following use of MIOSTAT*, either in clinical trials or via spontaneous post-market reporting, include the following:

Eye disorders: corneal clouding or opacity, persistent bulbous keratopathy, retinal detachment, post-operative iritis following cataract extraction, intraocular pressure increased, visual impairment, corneal degeneration, anterior chamber inflammation, corneal edema, eye inflammation, drug effect prolonged (miosis), vision blurred, eye pain, ocular hyperaemia
Gastrointestinal disorders: vomiting
Nervous system disorders: headache

Systemic reactions, such as flushing, sweating, epigastric distress, abdominal cramps and tightness in urinary bladder have been reported with topical or systemic application of carbachol.

DRUG INTERACTIONS

No clinically relevant drug interactions have been described.

DOSAGE AND ADMINISTRATION

Aseptically remove the sterile vial from the blister package by peeling the backing paper and dropping the vial onto a sterile tray. Withdraw the contents into a dry sterile syringe, and replace the needle with an atraumatic cannula prior to intraocular instillation. No more than one-half millimeter should be gently instilled into the anterior chamber for the production of satisfactory miosis. It may be instilled before or after securing sutures. Miosis is usually maximal within two to five minutes after application.

OVERDOSAGE

In case of overdose, symptoms of toxicity may include headache, salivation, syncope, bradycardia, hypotension, abdominal cramps, vomiting, asthma and diarrhea. Treatment of overdose is supportive. In cases of severe systemic toxicity, therapy with anticholinergic may be necessary.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

ACTION AND CLINICAL PHARMACOLOGY

Carbachol is a potent cholinergic (parasympathomimetic) agent, which produces constriction of the iris and ciliary body resulting in a reduction in intraocular pressure (IOP). The exact mechanism by which carbachol lowers IOP is not precisely known.

STORAGE AND STABILITY

Store at controlled room temperature ($15^{o}C – 30^{o}C$). Keep out of the reach and sight of children.

DOSAGE FORMS, COMPOSITION AND PACKAGING

MIOSTAT* is a sterile balanced salt solution of carbachol for intraocular injection.
Each mL contains:
Medicinal ingredient: carbachol 0.01% w/v
Non-medicinal ingredients: sodium chloride, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate, sodium acetate trihydrate, sodium citrate dihydrate, sodium hydroxide and/or hydrochloric acid (to adjust pH) and water for injection

MIOSTAT* is available in 1.5 mL sterile glass vials packaged twelve to a carton.

PART III: CONSUMER INFORMATION

Pr MIOSTAT*
Carbachol Intraocular Solution, USP

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MIOSTAT*. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
MIOSTAT* is used to:
- Constrict the pupil *(miosis)* during eye surgery
- Reduce the level of intraocular pressure (IOP) increase during the first 24 hours following cataract surgery

What it does:
MIOSTAT* contains carbachol, which constricts the iris (part of the eye which controls the pupil size) and the ciliary body (part of the eye that controls the shape of the lens) of the eye, thereby lowering the pressure in the eye (IOP).

When it should not be used:
Do not use MIOSTAT* if you are allergic *(hypersensitive)* to carbachol, natural rubber (latex) or any of the other ingredients of this medicine (see What the important nonmedicinal ingredients are).

What the medicinal ingredient is:
Carbachol, 0.01% w/v

What the important nonmedicinal ingredients are:
Calcium chloride dihydrate, magnesium chloride hexahydrate, potassium chloride, sodium acetate trihydrate, sodium citrate dihydrate, sodium chloride, sodium hydroxide and/or hydrochloric acid (to adjust pH) and water for injection.

What dosage forms it comes in:
MIOSTAT* is a sterile salt-balanced solution and is available in 1.5 mL glass vials.

WARNINGS AND PRECAUTIONS

BEFORE you use MIOSTAT* talk to your doctor or pharmacist if you:
- Have heart problems
- Have asthma
- Have a urinary tract obstruction (e.g. difficultly urinating)
- Have stomach ulcers *(peptic ulcers)*
- Have an overactive thyroid *(hyperthyroidism)*
- Have painful stomach cramping sensations
- Parkinson's disease
- Are allergic to natural rubber (latex). The vial stopper contains latex.

MIOSTAT* may increase eye inflammation following eye surgery.

Driving and Using Machinery
MIOSTAT* may cause blurred vision and difficulty in seeing in low light. Do not drive or use machinery until these effects have worn off.

Pregnancy and Breastfeeding
If you are pregnant, may be pregnant, are breastfeeding, or planning to breastfeed , talk to your doctor before using MIOSTAT*.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor about all the drugs you are using or planning to use, including those without a prescription. No drug interaction studies have been done for MIOSTAT*.

PROPER USE OF THIS MEDICATION

Usual adult dose:
MIOSTAT* is for injection into the eye and should only be administered by your doctor.

Overdose:
If excess MIOSTAT* is given, your doctor may need to give you an injection of an anticholinergic agent to control symptoms.

Symptoms of an overdose may include: headache, excess saliva, fainting, slow heart rate, a drop in blood pressure, abdominal cramps, vomiting, asthma and diarrhea.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, MIOSTAT* can cause side effects, although not everybody gets them.

Side effects include:
- Headache, flushing, sweating, stomach cramps, vomiting, bladder tightness (e.g. pressure in the bladder, feeling the need to urinate)
- Visual impairment (some difficulty in seeing), clouding of the eye surface, eye inflammation, blurred vision, eye swelling, eye pain, eye redness, increased eye pressure, decrease in pupil size

This is not a complete list of side effects. For any unexpected effects while taking MIOSTAT*, contact your doctor or pharmacist.

HOW TO STORE IT

Your doctor or another healthcare professional will store MIOSTAT*at controlled room temperature (15°C to 30°C), and keep it out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701D
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full prescribing information, prepared for health professionals can be found at:
http://www.alcon.ca
or by contacting the sponsor, Alcon Canada Inc. at:
1-800-613-2245

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