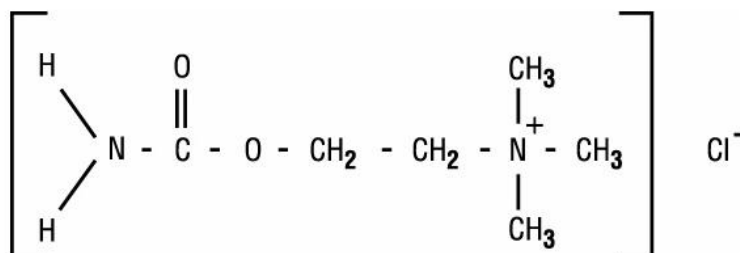


MIOSTAT®
(carbachol) Intraocular Injection 150 µg/1.5 mL

NAME OF MEDICINE

MIOSTAT (carbachol 0.01%) is a sterile balanced salt solution of carbachol for intraocular injection. The active ingredient is represented by the chemical structure:



Established name: Carbachol.
Chemical name: 2-[(aminocarbonyl)oxy]-N,N,N-trimethylethanaminium chloride.
CAS Registry Number: 51-83-2.

DESCRIPTION

Each 1.5 mL contains:

Active: carbachol 150 µg.

Inactive: sodium chloride 9.6 mg, potassium chloride 1.125 mg, calcium chloride 720µg, magnesium chloride 450 µg, sodium acetate 5.85 mg, sodium citrate 2.55 mg, sodium hydroxide and/or hydrochloric acid (to adjust pH), Water for Injections.

PHARMACOLOGY:

Carbachol is a potent cholinergic (parasympathomimetic) agent.

INDICATIONS:

Intraocular use for miosis during surgery.

CONTRAINDICATIONS:

Should not be used in those persons showing hypersensitivity to any of the components of this preparation.

PRECAUTIONS:

For single-dose intraocular use only.

Discard unused portion.

Intraocular carbachol 0.01% should be used with caution in patients with acute cardiac failure, bronchial asthma, peptic ulcer, hyperthyroidism, G.I. spasm, urinary tract obstruction and Parkinson's disease.

The use of intraocular carbachol may increase surgically induced intraocular inflammation.

Carcinogenicity: Studies in animals to evaluate the carcinogenic potential have not been conducted.

Use in Pregnancy:

Category B2- There are no adequate and well-controlled studies in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of intraocular carbachol during pregnancy. Carbachol should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Use in Lactation: It is not known if carbachol is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when carbachol is administered to a breastfeeding woman. Therefore, use only when considered essential by the physician.

Paediatric Use: Safety and efficacy in paediatric patients have not been established.

Interactions with Other Medicines

No clinically relevant interactions have been described with intraocular carbachol.

Effects on Ability to Drive and Use Machines

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

ADVERSE EFFECTS:

Ocular: Corneal clouding, persistent bullous keratopathy and post-operative iritis following cataract extraction with utilisation of intraocular carbachol have been reported with the occasional patient. As with all miotics, retinal detachment has been reported when miotics are used in certain susceptible individuals.

Systemic: Side effects such as flushing, sweating, epigastric distress, abdominal cramps, tightness in urinary bladder and headache have been reported after systemic or topical use of carbachol. These symptoms were not reported following intraocular use of carbachol in pre-marketing studies.

Post-Marketing Events

The following adverse reactions are classified according to the following convention: very common ($\geq 1/10$), common ($\geq 1/100$ to $<1/10$), uncommon ($\geq 1/1,000$ to $<1/100$), rare ($\geq 1/10,000$ to $<1/1,000$), very rare ($<1/10,000$), or not known (cannot be estimated from the available data), according to system organ classes. Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness. The adverse reactions have been observed during clinical trials and post-marketing experience with intraocular carbachol:

Nervous system disorders:

Uncommon ($\geq 0.1\%$ to $< 1\%$): headache

Eye disorders:

Uncommon ($\geq 0.1\%$ to $< 1\%$): intraocular pressure increased

Not Known: corneal opacity, anterior chamber inflammation, corneal oedema, eye inflammation, visual impairment, drug effect prolonged (miosis), vision blurred, eye pain, ocular hyperaemia.

Gastrointestinal disorders:

Not Known: vomiting

DOSAGE AND ADMINISTRATION:

This is not a multidose container and should not be used for more than one patient. Contains no antimicrobial agent. Use once only and discard any residue.

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 irrigation. No more than one-half mL 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 diarrhoea.

Treatment of overdose is supportive. In cases of severe systemic toxicity therapy with anticholinergics may be necessary. Atropine should be administered parenterally (for dosage refer to Goodman and Gilman or other pharmacology reference).

In Australia, contact Poisons Information Centre on 13 11 26; in New Zealand call 0800 POISON or 0800 764 766 for advice on management.

PRESENTATION AND STORAGE:

1.5 mL vials; packed twelve to a carton or as single vials when supplied with CUSTOM-PAK®.

Store below 25° C. Do not freeze.

NAME AND ADDRESS OF SPONSOR

This product is supplied in Australia by:

Alcon Laboratories (Australia) Pty Ltd

25 Frenchs Forest Road

Frenchs Forest NSW 2086

In New Zealand this product is distributed by:

Alcon New Zealand Limited

c/o Pharmaco (NZ) Limited

4 Fisher Crescent

Mt Wellington Auckland

POISON SCHEDULE OF MEDICINE

Prescription Only Medicine (Schedule 4)

DATE OF APPROVAL

Product Information approved by Therapeutic Goods Administration: 29 June 1992.

Single-vial presentation approved by Therapeutic Goods Administration: 17 November 1997.

Date of most recent amendment: 17 May 2011

® Registered Trademark

486440-0601