

## NEW ZEALAND DATA SHEET

### 1. PRODUCT NAME

MIOSTAT™ (carbachol) Intraocular Injection 150 µg/1.5 mL.

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

MIOSTAT™ injection contains carbachol 150 µg in 1.5 mL.

### 3. PHARMACEUTICAL FORM

Sterile solution for injection.

### 4. CLINICAL PARTICULARS

#### 4.1. Therapeutic indications

Intraocular use for miosis during surgery.

#### 4.2. Dose and method of administration

This is not a multi-dose 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.

#### 4.3. Contraindications

Should not be used in those persons showing hypersensitivity to any of the components of this preparation. See Section 6.1. List of excipients.

#### 4.4. Special warnings and precautions for use

**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.

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

## Paediatric population

Safety and efficacy in paediatric patients have not been established.

### **4.5 Interactions with other medicinal products and other forms of interactions**

No clinically relevant interactions have been described with intraocular carbachol.

### **4.6 Fertility, pregnancy and lactation**

#### 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.

#### Breast-feeding

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.

#### Fertility

Studies have not been performed to evaluate the effect of topical ocular administration of carbachol on human fertility.

### **4.7 Effects on ability to drive or 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.

### **4.8 Undesirable 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, corneal degeneration, drug effect prolonged (miosis), vision blurred, eye pain, ocular hyperaemia.

### *Gastrointestinal disorders*

Not Known: vomiting.

## Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting>.

## **4.9 Overdose**

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<sup>1</sup> or other pharmacology reference).

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764 766).

## **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Antiglaucoma preparations and miotics;  
Parasympathomimetics. ATC code: S01EB02.

### **5.1 Pharmacodynamic properties**

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<sup>1</sup> Goodman and Gilman's The Pharmacological Basis of Therapeutics.  
Internal document code  
MioS170820iNZ

### Mechanism of action

Carbachol is a potent cholinergic (parasympathomimetic) agent.

### Pharmacodynamic effects

Not available.

### Clinical efficacy and safety

Not available.

## **5.2 Pharmacokinetic properties**

Not available.

## **5.3 Preclinical safety data**

Not available.

### Carcinogenicity

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

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of excipients**

Sodium chloride

Potassium chloride

Calcium chloride

Magnesium chloride

Sodium acetate

Sodium citrate

Sodium hydroxide and/or hydrochloric acid (to adjust pH)

Water for Injections.

### **6.2 Incompatibilities**

Not available.

### **6.3 Shelf life**

36 months.

### **6.4 Special precautions for storage**

Store below 25°C. Do not freeze.

## **6.5 Nature and contents of container**

1.5 mL vials; packed twelve to a carton or as single vials when supplied with CUSTOM-PAK™. The vial stopper contains natural rubber (latex).

## **6.6 Special precautions for disposal**

Not available.

## **7. MEDICINE SCHEDULE**

Prescription Only Medicine.

## **8. SPONSOR**

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## **9. DATE OF FIRST APPROVAL**

20 October 1977.

## **10. DATE OF REVISION OF THE TEXT**

17 August 2020.

Summary Table of Changes

All sections.	Updated to SPC format.
8. SPONSOR	Update sponsor name, address and phone number.
All	Update trademark information.

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