

# MIOSTAT™

## Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using MIOSTAT?

MIOSTAT contains the active ingredient carbachol. This medicine works by stimulating the muscles inside the eye and is used to make your pupils constrict during eye surgery.

For more information, see Section 1. Why am I using MIOSTAT? in the full CMI.

### 2. What should I know before I use MIOSTAT?

Do not use if you have ever had an allergic reaction to MIOSTAT or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section 2. What should I know before I use MIOSTAT? in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with MIOSTAT and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

### 4. How do I use MIOSTAT?

- The amount of MIOSTAT Injection will be determined and administered by your doctor.
- MIOSTAT is only to be used by your doctor.

More instructions can be found in Section 4. How do I use MIOSTAT? in the full CMI.

### 5. What should I know while using MIOSTAT?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using MIOSTAT.</li><li>• Tell your doctor as soon as possible if you do not feel well after using MIOSTAT.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use the medicine after the expiring date has passed.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• You should not drive or operate any machinery after you have been given MIOSTAT.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• MIOSTAT is usually stored in the doctor's surgery or hospital, or at the pharmacy.</li><li>• If you need to store MIOSTAT keep it in a cool, dry place, out of the reach of children, where the temperature stays below 25° C. Do not freeze.</li></ul>

For more information, see Section 5. What should I know while using MIOSTAT? in the full CMI.

### 6. Are there any side effects?

All medicines can have side effects although not everybody gets them. The most common side effects of MIOSTAT include reactions at or near the site of injection. Less common side effects can include strong taste in the mouth, nausea and/or headache, gastrointestinal discomfort, abdominal pain, dizziness, light-headed or fainting, fatigue, etc.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

# MIOSTAT™

Active ingredient(s): carbachol

## Consumer Medicine Information (CMI)

This leaflet provides important information about using MIOSTAT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MIOSTAT.**

### Where to find information in this leaflet:

1. Why am I using MIOSTAT?
2. What should I know before I use MIOSTAT?
3. What if I am taking other medicines?
4. How do I use MIOSTAT?
5. What should I know while using MIOSTAT?
6. Are there any side effects?
7. Product details

## 1. Why am I using MIOSTAT?

**MIOSTAT contains the active ingredient carbachol.** This medicine works by stimulating the muscles inside the eye that are responsible for the contraction of the pupils.

Your doctor will inject MIOSTAT into your eyes to constrict your pupils during surgery.

**Ask your doctor if you have any questions or concerns about why this medicine has been used on your eye(s).**

## 2. What should I know before I use MIOSTAT?

### Warnings

#### Do not use MIOSTAT if:

- You are allergic to carbachol, any of the ingredients listed at the end of this leaflet or any other similar medicines.
- You are allergic to natural latex
- Always check the ingredients to make sure you can use this medicine.
- Some of the symptoms of an allergic reaction may include:
  - shortness of breath,
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue, or other parts of the body
  - rash, itching or hives on the skin.
- Do not use MIOSTAT if the expiry date has passed, the vial/package shows signs of tampering. If this

medicine is used after the expiry date has passed, it may not work as well.

- If you are not sure whether you should be given MIOSTAT talk to your doctor.

### Check with your doctor if you:

- Have any medical conditions, especially the following:
  - Heart failure
  - Asthma
  - Stomach ulcer
  - Stomach spasm
  - Hyperthyroidism which is caused by an overactive thyroid gland
  - Urinary tract obstruction
  - Parkinson's disease
- Have had an allergy to any other medicines or any other substances, such as foods, preservatives, or dyes.
- take any medicines for any other conditions.

If you have not told your doctor about any of the above, tell them before they administer MIOSTAT injection.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the possible risks and benefits of using MIOSTAT during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor will discuss the possible risks and benefits of using MIOSTAT when breastfeeding.

### Use in children

The safety and effectiveness of MIOSTAT Injection has not been established.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MIOSTAT.**

Your doctor will advise you and decide whether or not to give you MIOSTAT.

## 4. How do I use MIOSTAT?

### How much to use

- MIOSTAT is given as an injection into the eye(s) by your doctor.
- Your doctor will decide on the amount of MIOSTAT to be put into your eye(s)

### When to use MIOSTAT

MIOSTAT is used during eye surgery.

### If you forget to use MIOSTAT

Not applicable as MIOSTAT is only used by your doctor during surgery.

### If you are given too much MIOSTAT

If you think that you have been given too much MIOSTAT, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

## 5. What should I know while using MIOSTAT?

### Driving or using machines

You should not drive or operate any machinery after you have been given MIOSTAT.

As with any eye medicines, temporary blurred vision or other visual disturbances may affect the ability to drive or use machinery in some people. If blurred vision occurs, wait until your vision is clear before driving or operating machinery.

### Looking after your medicine

MIOSTAT is usually stored in the doctor's surgery or hospital, or at the pharmacy.

However, if you need to store MIOSTAT keep it in a cool, dry place where the temperature stays below 25°C. Do not freeze MIOSTAT.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep MIOSTAT and all other medicine in a safe place.

Keep it where children cannot reach it. A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

Tell your doctor as soon as possible if you do not feel well following the use of MIOSTAT.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• Flushing</li><li>• Sweating</li><li>• Stomach cramps or pain</li><li>• Headache</li><li>• Blurred vision</li><li>• Gradual loss of vision</li><li>• Redness in the eye</li><li>• Clouding, blistering or swelling of the front of the eye</li><li>• Eye pain, sensitivity to light</li><li>• Sensation of fullness in the bladder</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Very serious side effects:</b></p> <ul style="list-style-type: none"><li>• Sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body heartbeat.</li><li>• Retinal detachment has been reported when used in certain susceptible individuals. Symptoms include seeing bright flashes of light with floaters, progressing to a loss of sight.</li></ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the

Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor, nurse, or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What MIOSTAT contains

<b>Active ingredient (main ingredient)</b>	Carbachol 150 µg in 1.5 mL (0.01%)
<b>Other ingredients (inactive ingredients)</b>	Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate, Sodium citrate dihydrate, Sodium hydroxide and/or hydrochloric acid (to adjust pH), Water for Injections.
<b>Potential allergens</b>	The vial stopper contains natural rubber (latex).

**Do not use this medicine if you are allergic to any of these ingredients.**

### What MIOSTAT looks like

MIOSTAT is a clear solution that comes in a 1.5 mL vial. (AUST R 40624)

### Who distributes MIOSTAT

MIOSTAT is distributed in Australia by:

Alcon Laboratories (Australia) Pty Ltd

ABN 88 000 740 83054

15 Talavera Road

Macquarie Park NSW 2113

Telephone: 1800 224 153

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You should ensure that you speak to your doctor to obtain the most up to date information on the medicine.

You can also obtain a copy of the most up to date leaflet from your pharmacist. The updates may contain important information about the medicine and its use of which you should be aware.