MIOSTAT® Intraocular Solution for Injection

Carbachol

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MIOSTAT®
Intraocular Solution for Injection.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you having MIOSTAT against the benefits they expect it will have for you.

If you have any concerns about having this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

How MIOSTAT works

This medicine belongs to a group of medicines called parasympathomimetics.

It works by stimulating the muscles inside the eye that are responsible for the contraction of the pupils.

This medicine is not addictive.

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

Before you are given MIOSTAT

When you must not be given it

Do not have MIOSTAT® Intraocular Solution administered if you have an allergy to:

- any medicine containing carbachol
- any of the ingredients listed at the end of this leaflet.

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 give this medicine to a child.

Safety and effectiveness in children have not been established.

Do not have MIOSTAT administered after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should have MIOSTAT, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- · heart failure
- asthma

- ulcer in the stomach or duodenum
- hyperthyroidism (a condition caused by an overactive thyroid gland, causing an increase in metabolism. Symptoms include a fast heart rate and high blood pressure)
- spasm of the gastrointestinal tract
- urinary tract obstruction
- Parkinson's disease (a disease of the brain affecting movement)

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given MIOSTAT® Intraocular Solution.

Taking other medicines

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

Some medicines and MIOSTAT may interfere with each other.

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

How MIOSTAT is given

MIOSTAT is given as an injection into the eye(s) by a doctor or nurse during surgery.

How much is given

The amount of MIOSTAT to be instilled into your eye(s) during surgery is determined by your doctor.

If you use too much (overdose)

Your doctor will ensure that you are given the correct dose of MIOSTAT intraocular solution.

After having MIOSTAT® Intraocular Solution

Things to be careful of

Be careful driving or operating machinery until you know how MIOSTAT affects you.

MIOSTAT may cause blurred or decreased vision in some people, particularly under poor lighting conditions. Make sure you know how you react to MIOSTAT or that your vision is clear before driving a car or operating machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after having MIOSTAT.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Flushing
- Sweating
- Stomach cramps or pain

- Headache
- Blurred vision
- · Gradual loss of vision
- Redness in the eye
- Clouding, blistering or swelling of the front of the eye
- Eye pain, sensitivity to light
- Sensation of fullness in the bladder

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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.
- 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).

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Storing Miostat® Intraocular Solution

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 leave MIOSTAT in the car, in the bathroom or in other warm, damp places. Heat and temperature can destroy some medicines.
- Do not freeze MIOSTAT.

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.

Product description

What it looks like

MIOSTAT is a clear solution that comes in a 1.5 mL vial.

The vial stopper contains natural rubber (latex).

Ingredients

Active drug:

Carbachol

Other ingredients:

- Sodium chloride;
- potassium chloride;
- calcium chloride dihydrate;
- magnesium chloride hexahydrate;
- sodium citrate dihydrate;
- sodium acetate trihydrate;
- sodium hydroxide;
- hydrochloric acid;
- water for injections.

Supplier

In Australia this product is supplied by:

Alcon Laboratories (Australia) Pty Ltd

25 Frenchs Forest Road Frenchs Forest NSW 2086

AUST R 40624

In New Zealand this product is distributed by:

Alcon New Zealand Limited c/o Pharmaco (NZ) Limited 4 Fisher Crescent Mt Wellington New Zealand

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