MIOSTAT[™] Intraocular Solution for Injection 150 µg in 1.5 mL

Carbachol

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Please read this leaflet carefully before you are given $Miostat^{TM}$.

This leaflet answers some common questions about Miostat Solution for Injection. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

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

You can also download the most up to date leaflet from www.medsafe.govt.nz.

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of using Miostat against the risks this medicine could have for you.

The information in this leaflet applies to Miostat only. This information does not apply to similar products, even if they contain the same ingredients. If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Miostat is used for

Miostat contains carbachol which belongs to a group of medicines called parasympathomimetics.

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 to eye to constrict your pupils during surgery.

Ask your doctor if you have any questions about why this medicine is being used.

Use in children

The safety and effectiveness of Miostat Solution for Injection has not been established.

Before you are given Miostat

When you must not be given it

Miostat should not be given to you if you have an allergy to:

• Carbachol

- Any of the ingredients in Miostat which are listed under Product Description.
- Natural latex.

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.

Miostat should not be used if:

- the vial/packaging shows signs of tampering
- the expiry date on the injection vial/carton has passed.

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

If you are not sure whether Miostat should be used in your case, talk to your doctor.

This medicine has been developed for use in the eye only. It is not to be swallowed or injected.

Before you are given it

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

Tell your doctor if you have or have had 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.

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

Your doctor will discuss the possible risks and benefits of using $Miostat^{TM}$ during pregnancy.

Tell your doctor if you are breast-feeding or intend to breast-feed.

Your doctor will discuss the possible risks and benefits of using Miostat during breast-feeding.

If you have not told your doctor about any of the above, tell them before you are given Miostat.

Ask your doctor for advice on the risks and benefits involved.

Taking or using other medicines

Tell your doctor or pharmacist if you are taking or using any other medicines, including medicines that you buy at a pharmacy or health food shop without a doctor's prescription.

Your doctor will decide whether or not to give you Miostat.

How Miostat is given

How much is used

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

If you are given too much (overdose)

The doctor giving you Miostat will be experienced in the use of this medicine, so it is unlikely that you will be given an overdose.

If you feel you have been given too much Miostat immediately telephone your doctor or the National Poisons Centre on 0800 POISON 0800 764 766 for advice, or go to Accident and Emergency at the nearest hospital.

After you are given Miostat

Things to be careful of

Be careful driving or operating machinery until you know how Miostat affects you and your vision.

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.

Side Effects

Tell your doctor as soon as possible if you do not feel well after Miostat use.

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

Do not feel alarmed the list of possible side effects. You may not experience any of them.

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

Tell your doctor, nurse 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.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you experience any of the following symptoms:

- 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 if you notice any unwanted effects even if they do not appear in the list above.

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

After using Miostat

Storage

MIOSTATTM 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.

Do not leave Miostat in the car, in the bathroom or in other warm, damp places.

Heat and temperature can destroy some medicines.

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.

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

Miostat contains carbachol 150 μ g in 1.5 mL as the active ingredient.

It also contains:

- Sodium chloride
- Potassium chloride
- Calcium chloride
- Magnesium chloride
- Sodium acetate
- Sodium citrate
- Sodium hydroxide and/or hydrochloric acid (to adjust pH)
- Water for Injections.

Supplier

Miostat is supplied in New Zealand by:

Alcon Laboratories (New Zealand) Limited

12 St Marks Road

Remuera

Auckland 1050

New Zealand.

PO Box 9413

Newmarket

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New Zealand.

Free Phone: 0800 101 106.

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