

PACKAGE LEAFLET

Package leaflet: Information for the user

Miostat (carbachol) 100 microgram/ml solution for injection for intraocular use

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Miostat is and what it is used for
2. What you need to know before you use Miostat
3. How to use Miostat
4. Possible side effects
5. How to store Miostat
6. Content of the pack and other information

1. What Miostat is and what it is used for

Miostat is used during eye surgery when rapid and complete pupil constriction is desired. The maximal constriction usually occurs within a few minutes after application. Miostat is only used during eye surgery.

2. What you need to know before you use Miostat

Do not use Miostat:

- if you are hypersensitive (allergic) to the active substance or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Take special care with Miostat:

If your doctor is unaware that you suffer from any of the following conditions, please inform your doctor before this medicine is used:

- Iritis (acute or chronic inflammation of the coloured portion of your eye).
- Acute heart failure.
- Asthma.
- Peptic ulcer.
- Abnormal thyroid function.
- Gastrointestinal spasm.
- Urinary tract obstruction.
- Parkinson's disease.
- **The vial stopper contains natural rubber (latex).** Which may cause severe allergic reactions

Pregnancy, breast feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist before using Miostat.

Driving and using machines

Miostat may cause blurred vision and sensitivity to light. If temporary blurred vision occurs after your eye surgery, you must wait until your vision clears before driving or using machinery.

Other medicines and Miostat

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Miostat can influence the effects of cardiac glycosides (like digoxin) or some muscle relaxants used during anaesthesia.

3. How to use Miostat

Miostat should be applied only by your doctor before eye surgery.

A maximum of 0.5 ml Miostat is injected into the anterior chamber of the eye during eye surgery. The effect of Miostat may last for up to 24 hours following your eye surgery.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them

Uncommon side effects

(may affect up to 1 in 100 people)

- Headache
- Increased pressure in the eye

Rare side effects

(may affect up to 1 in 1000 people)

- Swelling, clouding or other damage to the cornea
- Inflammation of structures inside your eye (iritis, uveitis)
- Temporary decrease or blurring of vision
- Retinal detachment

Not known

(frequency cannot be estimated from the available data)

- Visual impairment, drug effect prolonged, eye pain, eye redness
- Nausea, vomiting, stomach upset.

Eye drops that constrict the pupil may cause the following side effects:

Redness of the eye, blurred vision, sensitivity to light, retinal detachment.

In other parts of your body: Headache, flushing, sweating, upset stomach, abdominal cramps, urinary urgency.

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to Store Miostat

Keep this medicine out of the sight and reach of children.

There are no special storage instructions.

Miostat shall be used immediately following opening.

Do not use Miostat after the expiry date shown on the carton and vial. Discard unused portion.

6. Content of the pack and other Information

What Miostat contains

1 ml solution contains 100 micrograms carbachol.

One 1.5 ml vial contains 150 micrograms carbachol.

The active substance is carbachol 100 microgram/ml.

- The other ingredients are: sodium chloride, potassium chloride (E508), calcium chloride (E509), magnesium chloride (E511), sodium acetate (E262), sodium citrate (E311), sodium hydroxide (E524) and/or hydrochloric acid (E507) (to adjust the acidity level), water for injection solutions.

Marketing Authorisation Holder:

<to be completed locally>

Manufacturer:

S.A. Alcon-Couvreur N.V.
Rijksweg 14
B-2870 Puurs
Belgium

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