

NEW ZEALAND DATA SHEET

1 MIOCHOL®-E Acetylcholine chloride 20mg/2mL Intraocular Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 mL of solution contains 20 mg of acetylcholine chloride.
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder and diluent for intraocular injection.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Miochol®-E is used to obtain miosis of the iris in seconds after placement of the IOL (intraocular lens) in cataract surgery and in penetrating keratoplasty, iridectomy and other anterior segment surgery where rapid miosis may be required.

4.2 Dose and method of administration

In most cases 0.5 to 2.0 mL produces satisfactory miosis.

The syringe containing the reconstituted preparation must be fitted with a suitable irrigation cannula for intraocular irrigation.

The Miochol®-E solution is instilled into the anterior chamber before or after securing one or more sutures. Instillation should be gentle and parallel to the iris face and tangential to pupil border.

If there are no mechanical hindrances, the pupil starts to constrict in seconds and the peripheral iris is drawn away from the angle of the anterior chamber. Any anatomical hindrance to miosis, such as anterior or posterior synechiae, must be released to permit the desired effect of the drug.

The solution should be reconstituted immediately before use since aqueous solutions of acetylcholine are unstable.

Instructions for Use and Handling

Warning: Do not use if blister or peelable backing is damaged or broken. Open under aseptic conditions only, at the time of surgery.

Directions for Preparing Miochol-E:

1. Inspect unopened blister to ensure that it is intact. The outer package is not sterile. Peel open blister.

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2. Aseptically transfer the ampoule, vial and filter hub to sterile field. Maintain asepsis during preparation of solution. Sterile gloves and gowns should be used.
3. Aseptically attach a sterile 18 to 20 gauge, bevelled needle to the luer tip of a sterile disposable syringe with twisting motion to assure secure fit.
4. Break open the ampoule containing the diluent. The One Point Cut (OPC) ampoule must be opened as follows: hold the bottom part of the ampoule with the thumb pointing to the coloured point; grasp the top of the ampoule with the other hand, positioning the thumb at the coloured point and press back to break at the existing cut under the point.
5. Remove the needle protector and withdraw the diluent from the ampoule into the syringe. Discard ampoule.
6. Remove and discard plastic cap from top of vial.
7. Insert the needle through the centre of the vial stopper.
8. Transfer the diluent from the syringe to the vial.
9. Shake gently to dissolve drug.
10. Slowly withdraw the solution from the vial through the needle into the syringe.
11. Discard needle.
12. Aseptically open filter hub pouch.
13. Aseptically attach filter hub onto luer tip of syringe with a twisting motion to assure secure fit.
14. Aseptically attach a sterile blunt tip irrigation cannula to male luer of filter prior to intraocular irrigation.
15. Discard appropriately after use. Do not reuse the filter hub.
16. The solution must be mixed just before use, since aqueous solutions of acetylcholine are unstable. Only clear and colourless solutions should be used. To reduce microbiological hazard, use as soon as practicable after reconstitution. If storage is necessary, hold at 2-8°C for not more than 6 hours. Any residual quantities of acetylcholine chloride solution should be discarded after a maximum of 6 hours for stability reasons.

Contains no antimicrobial agent.

Miochol-E should not be re-sterilised. The filter hub is recommended only for use with Miochol-E. Aspiration through the filter is not recommended. However, if utilised, discard needle and syringe filter to prevent recontamination of fluids during injection.

Do not aspirate and inject through the same filter.

4.3 Contraindications

Known hypersensitivity to acetylcholine or to any of the excipients.

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4.4 Special warnings and precautions for use

In cataract surgery, use Miochol®-E only after the placement of the IOL.

Miochol®-E cannot be re-sterilised. Do not gas sterilise. If the blister or peelable backing is damaged or broken, sterility of the enclosed bottle cannot be assured. Open under aseptic conditions only.

Aqueous solutions of acetylcholine chloride are unstable. Prepare solution immediately before use. Only solutions that are clear and colorless should be used. Unused residual amounts should be discarded

4.5 Interaction with other medicaments and other forms of interaction

None known.

Paediatric population

Safety and effectiveness in children have not been established.

4.6 Fertility, pregnancy and lactation

Category B2. Animal reproduction studies have not been conducted with Miochol®-E. It is not known whether Miochol®-E can cause foetal harm when administered to pregnant women or can affect reproductive capacity. Miochol®-E should be given to pregnant women only if clearly needed.

It is not known whether Miochol®-E is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Miochol®-E is administered to nursing women.

4.7 Effects on ability to drive and use machines

Not relevant

4.8 Undesirable effects

Frequency	Ocular	Non-ocular
Uncommon (≥ 1/1000 and <1/100)	Corneal oedema, corneal clouding, corneal decompensation	None
Rare (≥ 1/10,000 and <1/1000)	None	Bradycardia, hypotension, flushing, breathing difficulties, sweating.

4.9 Overdose

Systemic toxicity is low because of rapid local breakdown. Symptoms of overdose are likely to be effects resulting from systemic absorption (see Adverse Reactions). In case of overdose, atropine sulfate (0.5 to 1 mg) should be given intramuscularly or intravenously

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and should be readily available. Adrenaline (0.1 to 1 mg sc) is also of value in overcoming severe cardiovascular or bronchoconstrictor responses.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Acetylcholine is a naturally occurring neurohormone which mediates nerve impulse transmission at all cholinergic sites involving somatic and autonomic nerves. After release from the nerve endings, acetylcholine is rapidly inactivated by the enzyme acetylcholinesterase by hydrolysis to acetic acid and choline.

Direct application of acetylcholine to the iris will cause rapid miosis of short duration. Topical ocular instillation of acetylcholine to the intact eye causes no discernible response as cholinesterase destroys the molecule more rapidly than it can penetrate the cornea.

Clinical studies with Miochol-E have shown it to be clinically and statistically superior to placebo in inducing miosis following cataract surgery when administered at doses of 0.5-2.0mL:

Horizontal Pupil Diameter (mm) for Intention to Treat Subjects (mean \pm SD)

	Post IOL	Post Injection +45 secs	Post Injection + 5-10 mins
Miochol-E (n=62) Change from post IOL P value - within treatment	7.4 \pm 1.5	5.1 \pm 1.5 -2.3 \pm 1.2 <0.001	4.6 \pm 1.4 -2.8 \pm 1.2 <0.001
Placebo (n=31) Change from post IOL P value - within treatment	7.1 \pm 1.3	6.8 \pm 1.4 -0.3 \pm 0.5 0.002	6.3 \pm 1.6 -0.8 \pm 0.8 <0.001

5.2 Pharmacokinetic properties

No data on the pharmacokinetics of topical acetylcholine chloride are available.

5.3 Preclinical safety data

Not available

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vial: mannitol.

Ampoule: sodium acetate, magnesium chloride, potassium chloride, calcium chloride, water for injections.

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6.2 Incompatibilities

Reconstitute the solution only with the supplied diluent.

The filter hub is recommended only for use with Miochol-E.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 25°C. Do not freeze.

6.5 Nature and contents of container

Miochol-E is presented in a blister pack containing one vial and one ampoule; the vial contains 20mg of acetylcholine chloride; the ampoule contains 2mL of diluent.

Miochol-E is supplied as packs containing 1 blister and 1 filter hubs with 5 micron filter, luer lock. Packs are subject to antimicrobial treatment with ethylene oxide.

Explanation of the symbols:



for single use only



lot number



expiry date



see instructions for use



manufacture date



sterilization with ethylene oxide



catalogue number

6.6 Special precautions for disposal

Product is for single use in one patient only. Discard any residue.

7 MEDICINE SCHEDULE

Prescription Medicine

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8 SPONSOR

Bausch & Lomb (NZ) Ltd
c/- Bell Gully
Auckland Vero Centre
48 Shortland Street
Auckland 1140
New Zealand

9 DATE OF FIRST APPROVAL

14 October 2004

10 DATE OF REVISION OF THE TEXT

30 Nov 2018

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All	Data sheet format update to comply with European Summary of Product Characteristics (SmPC) format.
8	Removal of Toll Free Number
9	Inclusion of First Approval Date