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BAUSCH+LOMB

# Miochol®-E

Parasympathomimetic

## COMPOSITION AND PHARMACEUTICAL FORM

Each vial contains 20 mg acetylcholine chloride. Miochol®-E contains 10mg/ml of acetylcholine chloride (20 mg in 2 ml) upon reconstitution.

For excipients, see section **EXCIPIENTS**.
Powder and solvent for instillation solution for intraocular use. Miochol®-E is presented in a blister pack containing one vial and one ampoule; the vial contains 20 mg of acetylcholine chloride; the ampoule contains 2 ml of solvent. The reconstituted preparation is a clear, colourless solution.

## INDICATIONS

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

## DOSAGE AND ADMINISTRATION

**Adults and elderly**
In most cases, 0.5 to 2 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 the 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.

**Paediatric use**
Safety and effectiveness in children have not been established.

## CONTRAINDICATIONS

Hypersensitivity to the active substance or to any of the excipients.

## SPECIAL WARNINGS AND PRECAUTIONS FOR USE

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

## INTERACTIONS

None known

## PREGNANCY AND LACTATION

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

**Lactation**
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.

## EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Not applicable.

## UNDESIRABLE EFFECTS

Infrequent cases of corneal oedema, corneal clouding, and corneal decompensation have been reported with the use of intraocular acetylcholine.
Adverse reactions indicative of systemic absorption have been reported rarely. These include bradycardia, hypotension, flushing, breathing difficulties and sweating.

## OVERDOSE

Systemic toxicity is low because of rapid local breakdown. Symptoms of overdose are likely to be effects resulting from systemic absorption (see section UNDESIRABLE EFFECTS).
In case of overdose atropine sulphate (0.5 to 1 mg) should be given intramuscularly or intravenously and should be readily available. Epinephrine (0.1 to 1 mg s.c.) is also of value in overcoming severe cardiovascular or bronchoconstrictor responses.

## PHARMACODYNAMICS

Acetylcholine is a naturally occurring neuro-hormone 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. The density of ocular parasympathetic receptors of the muscarinic type is high. They are localised:

- at the level of the pupillary sphincter, whose contraction causes miosis.
- at the level of the ciliary muscle, whose contraction allows accommodation and facilitates aqueous humour flow by opening the trabecular meshwork. In addition, acetylcholine can have an inhibitory effect on aqueous secretion. These two last factors result in a decrease in intraocular pressure.
- at the level of the lacrimal glands, whose excitation causes tearing.

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.

## PHARMACOKINETICS

Due to rapid hydrolysis of acetylcholine to acetic acid and choline by cholinesterases, there are no pharmacokinetic data.

## PRECLINICAL SAFETY DATA

There is no evidence of mutagenic, carcinogenic, or teratogenic potential by acetylcholine chloride.
Miochol®-E was well tolerated following intraocular injection of a dose of 0.5 ml/eye in cats.

## EXCIPIENTS

Each pack contains.

**Vial**
Mannitol

**Ampoule**
Sodium acetate, magnesium chloride, potassium chloride, calcium chloride, water for injections.

## INCOMPATIBILITIES

None known.
The filter hub is recommended only for use with Miochol®-E.

## STORAGE

Do not store above 25°C. Do not freeze.
Miochol®-E should not be used after the date marked "EXP" on the pack.

## INSTRUCTIONS FOR USE AND HANDLING

Warning: Do not use if blister or peelable backing is damaged or broken. Open under aseptic conditions only.

**Directions for Preparing Miochol®-E**

1. Inspect unopened blister to ensure that it is intact. Peel open blister.
2. Aseptically transfer the ampoule, vial and filter hub to sterile field. Maintain asepsis during preparation of solution.
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 solvent. 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 solvent 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 solvent 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.

The solution must be mixed just before use, since aqueous solutions of acetylcholine are unstable. Only clear and colourless solutions should be used.
Any residual quantities of acetylcholine chloride solution should be discarded after a maximum of 6 hours for stability reasons.
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 utilized, discard needle and syringe filter to prevent recontamination of fluids during injection.
Do not aspirate and inject through the same filter.

**Explanation to the symbols:**

For single use only
LOT Lot number
Expiry date
See instructions for use
Manufacture date
STERILE EO Sterilization with ethylene oxide
REF Catalogue number

Note: Miochol®-E should be kept out of the reach and sight of children.

**Product Owner**
Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY14609 USA

**Manufacturer**
Novartis Pharma Stein AG
Schaffhauserstrasse
4332 Stein
Switzerland

**Singapore Package Leaflet**
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