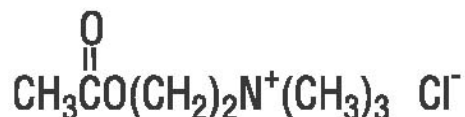


MIOCHOL[®]-E*(acetylcholine chloride intraocular solution)**1:100 with Electrolyte Diluent***Prescribing Information**

DESCRIPTION: MIOCHOL[®]-E (acetylcholine chloride intraocular solution) is a parasympathomimetic preparation for intraocular use. It is packaged in a blister pack containing one vial and one ampoule. The vial contains 20 mg acetylcholine chloride and 56 mg mannitol. The accompanying ampoule contains 2 mL of a modified diluent of sodium acetate trihydrate, potassium chloride, magnesium chloride hexahydrate, calcium chloride dihydrate and sterile water for injection.

The reconstituted liquid will be a sterile isotonic solution (275-330 milliosmoles/Kg) containing 20 mg acetylcholine chloride (1:100 solution) and 2.8% mannitol. The pH range is 5.0-8.2. Mannitol is used in the process of lyophilizing acetylcholine chloride, and is not considered an active ingredient.

The chemical name for acetylcholine chloride, C₇H₁₆ClNO₂, is Ethanaminium, 2-(acetyloxy)-N,N,N-trimethyl-, chloride and is represented by the following chemical structure:



CLINICAL PHARMACOLOGY: 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 ending, 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.

INDICATIONS AND USAGE: To obtain miosis of the iris in seconds after delivery of the lens in cataract surgery, in penetrating keratoplasty, iridectomy and other anterior segment surgery where rapid miosis may be required.

CONTRAINDICATIONS: MIOCHOL[®]-E (acetylcholine chloride intraocular solution) is contraindicated in persons with a known hypersensitivity to any component of this product.

WARNINGS: DO NOT GAS STERILIZE. If blister or peelable backing is damaged or broken, sterility of the enclosed vial and ampoule cannot be assured. Open under aseptic conditions only.

PRECAUTIONS: GENERAL:

If miosis is to be obtained quickly with MIOCHOL-E, anatomical hindrances to miosis, such as anterior or posterior synechiae, must be released, prior to administration of MIOCHOL-E. During cataract surgery, use MIOCHOL-E only after delivery of the lens.

Aqueous solutions of acetylcholine chloride are unstable. Prepare solution immediately before use. Do not use solution which is not clear and colorless. Discard any solution that has not been used.

DRUG INTERACTIONS: Although clinical studies with acetylcholine chloride and animal studies with acetylcholine or carbachol revealed no interference, and there is no known pharmacological basis for an interaction, there have been reports that acetylcholine chloride and carbachol have been ineffective when used in patients treated with topical nonsteroidal anti-inflammatory agents.

PEDIATRIC USE: Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS: Infrequent cases of corneal edema, corneal clouding, and corneal decompensation have been reported with the use of intraocular acetylcholine.

Adverse reactions have been reported rarely which are indicative of systemic absorption. These include bradycardia, hypotension, flushing, breathing difficulties and sweating.

OVERDOSAGE: Atropine sulfate (0.5 to 1 mg) should be given intramuscularly or intravenously and should be readily available to counteract possible overdose. Epinephrine (0.1 to 1 mg subcutaneously) is also of value in overcoming severe cardiovascular or bronchoconstrictor responses.

DOSAGE AND ADMINISTRATION:

The MIOCHOL-E (acetylcholine chloride intraocular 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 must be released to permit the desired effect of the drug. In most cases, 0.5 to 2 mL produces satisfactory miosis.

In cataract surgery, use MIOCHOL-E only after delivery of the lens.

Aqueous solutions of acetylcholine chloride are unstable. Prepare solution immediately before use. Do not use solution which is not clear and colorless. Discard any solution that has not been used.

DIRECTIONS FOR PREPARING MIOCHOL[®]-E:

STERILE UNLESS PACKAGE OPEN OR BROKEN

1. Inspect the unopened blister, vial and ampoule to ensure that they are all intact. Peel open the blister under a sterile field. Maintain sterility of the outer containers of the vial and ampoule during preparation of solution.
2. Aseptically attach a sterile 18-20 gauge, beveled needle to the luer tip of a sterile disposable syringe with a twisting motion to assure a secure fit.
3. Break open the ampoule containing the diluent. The One Point (OPC) ampoule must be opened as follows: Hold the bottom part of the ampoule with the thumb pointing to the colored dot. Grasp the top of the ampoule with the other hand, positioning the thumb at the colored dot, and press back to break at the existing cut under the dot.

4. Remove the needle protector and withdraw the diluent from the ampoule into the syringe. Discard the ampoule.
5. Remove and discard the cap from the top of the vial.
6. Insert the needle through the center of the vial stopper, and transfer the diluent from the syringe to the vial. Shake gently to dissolve the powder.
7. Slowly withdraw the solution from the vial through the needle into the syringe. Discard the needle.
8. Aseptically open the syringe filter pouch, and attach the filter onto the luer tip of the syringe with a twisting motion to assure a secure fit.
9. Aseptically attach a sterile blunt tip irrigation cannula to the male luer of the filter prior to intraocular irrigation.

Discard the filter appropriately after use.

Do not reuse the syringe filter.

Do not aspirate and inject through the same filter.

HOW SUPPLIED:

Miochol-E (acetylcholine chloride intraocular solution)

NDC 0078-0474-61

One blister pack containing the following components:

- Vial of 20mg acetylcholine chloride powder for intraocular solution
- Ampoule of 2 mL diluent
- One 0.2 micron sterile filter

Store at 4°-25°C (39°-77°F).

KEEP FROM FREEZING.

REV: March 2006 T2006-23

Rx Only



Manufactured by:

Novartis Pharma Stein AG

Stein, Switzerland

Distributed by:

Novartis Pharmaceuticals Corporation

East Hanover, New Jersey 07936

Carton Label:

