Miochol™-E  
(acetylcholine chloride intraocular solution)  
20 mg/2 mL (10 mg/mL)  
Sterile  
1:100 with Electrolyte Diluent  
Rx only  
FOR INTRAOCULAR USE ONLY

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 diluent ampule. The vial contains 20 mg acetylcholine chloride and 56 mg mannitol. The accompanying ampule contains 2 mL of a modified diluent of calcium chloride dihydrate, magnesium chloride hexahydrate, potassium chloride, sodium acetate trihydrate, 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, C\(_7\)H\(_{16}\)ClNO, is Ethanaminium, 2-(acetyloxy)-N,N,N-trimethyl-, chloride and is represented by the following chemical structure:

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\(\text{CH}_3\text{CO(CH}_2)_2\text{N+(CH}_3)_3\text{Cl}^-\)
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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 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 ampule 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.

To report SUSPECTED ADVERSE REACTIONS, contact Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

DOSAGE AND ADMINISTRATION
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. Note that the syringe filter supplied with Miochol-E has a priming volume of 0.6 mL (approximately).
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 that is not clear and colorless. Discard any solution that has not been used.

DIRECTIONS FOR PREPARING MIOCHOL™-E:

1. Inspect the unopened blister, vial, and ampule 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 ampule 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 ampule containing the diluent. The One Point Cut (OPC) ampule must be opened as follows: Hold the bottom part of the ampule with the thumb pointing to the colored dot. Grasp the top of the ampule 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 ampule into the syringe. Discard the ampule.
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 24208-539-20

One blister pack containing the following components:

- Vial of 20 mg acetylcholine chloride powder for intraocular solution
- Ampule of 2 mL diluent

One 0.2 micron sterile filter

- Priming volume 0.6 mL (approximately)

Storage
Store at 4°-25°C (39°-77°F)

KEEP FROM FREEZING
KEEP OUT OF REACH OF CHILDREN

Manufactured for:
Bausch + Lomb, a division of
Valeant Pharmaceuticals North America LLC
Bridgewater, NJ 08807 USA

Manufactured by:
Sanofi S.p.A.
Via Valcanello, 4
03012 ANAGNI (FR)

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PACKAGE/LABEL PRINCIPAL DISPLAY PANEL
Miochol™-E (acetylcholine chloride intraocular solution)

20 mg/2 mL (10 mg/mL)
Sterile

1:100 with Electrolyte Diluent

FOR INTRAOCULAR USE ONLY

Rx Only
Contents:
One Blister Pack containing:
- 20mg vial
- 2 mL diluent ampule
One 0.2 micron sterile filter

BAUSCH + LOMB

MIOCHOL E
acetylcholine chloride kit

Product Information
Product Type: HUMAN PRESCRIPTION DRUG
Item Code (Source): NDC:24208-539

Packaging

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<th>#</th>
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<th>Marketing End Date</th>
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Quantity of Parts

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<tr>
<td>Part 1</td>
<td>1 VIAL</td>
<td>2 mL</td>
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<tr>
<td>Part 2</td>
<td>1 AMPULE</td>
<td>2 mL</td>
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Part 1 of 2

MIOCHOL E
acetylcholine chloride solution

Product Information
Route of Administration: INTRAOCULAR

Active Ingredient/Active Moiety

<table>
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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>ACETYLCHOLINE CHLORIDE (UNII: AF73293C2R) (ACETYLCHOLINE - UNII:N9YNS0M02X)</td>
<td>ACETYLCHOLINE CHLORIDE</td>
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Inactive Ingredients

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<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>MANNITOL (UNII: 3OWL53L36A)</td>
<td>56 mg in 2 mL</td>
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Packaging

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Marketing Information

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<td>09/22/1993</td>
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Part 2 of 2
DILUENT
diluent solution

Product Information
Route of Administration
INTRAOCULAR

Inactive Ingredients

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<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tbody>
<tr>
<td>CALCIUM CHLORIDE (UNII: M4I0D6VV5M)</td>
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<tr>
<td>MAGNESIUM CHLORIDE (UNII: 02F3473H9O)</td>
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</tr>
<tr>
<td>POTASSIUM CHLORIDE (UNII: 660YQ98110)</td>
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<tr>
<td>SODIUM ACETATE (UNII: 4550K0SC9B)</td>
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<td>WATER (UNII: 059QF0KO0R)</td>
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Packaging

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<td>09/22/1993</td>
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Labeler - Bausch & Lomb Incorporated (196603781)

Establishment

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Revised: 5/2017