Miochol®-E

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about being given this medicine, speak to your doctor or pharmacist.

1. Why am I being given Miochol-E?

Miochol-E contains the active ingredient acetylcholine chloride. Miochol-E is used to constrict the pupil of the eye during surgery for removal of a cataract (the lens inside the eye) and other types of eye surgery.

For more information, see Section 1. Why am I being given Miochol-E? in the full CMI.

2. What should I know before being given Miochol-E?

Do not use if you are allergic to any medicine containing acetylcholine chloride or to any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section 2. What should I know before being given Miochol-E? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Miochol-E and affect how it works. Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Miochol-E.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is Miochol-E given?

Miochol-E is given as a single dose during eye surgery. Your doctor will prepare and administer Miochol-E for you. In most cases, 0.5 to 2 mL is enough to constrict the pupil of the eye sufficiently.

More information can be found in Section 4. How is Miochol-E given? in the full CMI.

5. What should I know while being given Miochol-E?

| Things you should do | • | Keep all of your doctor's appointments so that your progress can be checked. |
|---------------------------|---|---|
| Driving or using machines | • | Be careful before you drive or use any machines or tools until you know how Miochol-E affects you. It may cause blurred vision for a short time when it is instilled into the eye. Allow enough time to regain clear vision before driving or using machines. |

For more information, see Section 5. What should I know while being given Miochol-E? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them. Less serious side effects include: dizziness or lightheadedness due to low blood pressure, flushing, sweating, abnormal vision. Serious side effects include: slow heart rate, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

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Miochol®-E

Active ingredient: Acetylcholine chloride

Consumer Medicine Information (CMI)

This leaflet provides important information about being given Miochol-E. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being given Miochol-E.

Where to find information in this leaflet:

- 1. Why am I being given Miochol-E?
- 2. What should I know before being given Miochol-E?
- 3. What if I am taking other medicines?
- 4. How is Miochol-E given?
- 5. What should I know while being given Miochol-E?
- 6. Are there any side effects?
- Product details

1. Why am I being given Miochol-E?

Miochol-E contains the active ingredient acetylcholine chloride. Miochol-E belongs to a group of medicines called parasympathomimetics.

Miochol-E is used to constrict the pupil of the eye during surgery for removal of a cataract (the lens inside the eye) and other types of eye surgery.

2. What should I know before being given Miochol-E?

Warnings

Do not use Miochol-E if:

- You are allergic to any medicine containing acetylcholine chloride.
- You are allergic to any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

This medicine has been developed for use in the eye only. It should not be swallowed or injected.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or

supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Miochol-E may interfere with each other. These medicines may be affected by Miochol-E or may affect how well it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Miochol-E.

4. How is Miochol-E given?

Miochol-E is given as a single dose during eye surgery. If the surgery is for removal of a cataract, it is given following placement of a new lens inside the eye.

Your doctor will prepare and administer Miochol-E for you.

How much is given

In most cases, 0.5 to 2 mL is enough to constrict the pupil of the eye sufficiently.

How it is given

Miochol-E is made into a solution immediately before use. This solution is run through a small tube into the front chamber of the eye.

If you are given too much Miochol-E

If you are given more Miochol-E than you need, your doctor may need to give you an injection of either atropine sulfate or adrenaline to control symptoms.

Symptoms of overdose may include slow heart rate, low blood pressure, flushing, breathing difficulties and sweating.

Because acetylcholine is rapidly broken down by the body, symptoms of overdose are unlikely to occur.

5. What should I know while being given Miochol-E?

Things you should do

 Keep all of your doctor's appointments so that your progress can be checked.

Driving or using machines

Do not drive or operate machinery until you have recovered from your eye surgery and your vision is normal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Tell your doctor as soon as possible if you do not feel well while you are being treated with Miochol-E.

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See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

| Less serious side effects | What to do |
|--|--|
| dizziness or lightheadedness due to low blood pressure | Speak to your doctor if you |
| flushing, sweatingpain in the eyeblurred vision. | have any of these less serious side effects and they worry you. |

| Serious side effects | What to do |
|--|--|
| slow heart rate shortness of breath wheezing or difficulty breathing swelling of the face, lips, tongue or other parts of the body rash, itching or hives on the skin. | Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects online (in Australia, go to www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Miochol-E contains

| Active ingredient (main ingredient) | Acetylcholine chloride (10 mg/mL) | |
|--|---|--|
| Other ingredients (inactive ingredients) | mannitol sodium acetate magnesium chloride potassium chloride calcium chloride water for injection | |

Do not use this medicine if you are allergic to any of these ingredients.

What Miochol-E looks like

Miochol-E (AUST R 118510) comes in a clear glass vial and a glass ampoule: the vial contains a white powder (20 mg of acetylcholine chloride) and the ampoule contains a clear, colourless solution (2 mL of diluent for reconstitution of the powder). The contents are mixed immediately before use to form a clear, colourless solution.

Who distributes Miochol-E

In Australia, Miochol-E is supplied by: Bausch & Lomb (Australia) Pty Ltd Level 2, 12 Help Street Chatswood, NSW 2067

Phone: 1800 251 150

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