Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Miochol-E.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risk of you being given Miochol-E against the benefits they expect it will have for you.

If you have any concerns about being given Miochol-E, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Miochol-E is used for

Miochol-E is used to constrict the pupil of the eye during cataract surgery and other types of eye surgery.

It belongs to a group of medicines called parasympathomimetics.

It works by mediating nerve impulse transmission.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children.

Before you are given Miochol-E

When you must not be given it

You must not be given Miochol-E if you have an allergy to:

- any medicine containing acetylcholine chloride
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include 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.

You must not be given Miochol-E after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about the above, tell him/her before you are given Miochol-E.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Your doctor and pharmacist have more information on medicines to be careful with or avoid when you are given Miochol-E.

How Miochol-E is 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 the intraocular lens.

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(overdose)

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.

While you are being given Miochol-E

Things you must do

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

Things to be careful of

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

Side effects

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

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- · slow heart rate
- dizziness or lightheadedness due to low blood pressure
- breathing difficulties
- · flushing, sweating
- · abnormal vision.

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

Other side effects not listed above may also occur in some people.

New Zealand

Toll free number: 0508375394

Date of preparation

This leaflet was prepared in February 2018

AUST R 118510

Product description

What it looks like

Miochol-E comes in a vial and an ampoule: the vial contains a white powder and the ampoule contains a clear, colourless solution. The contents are mixed immediately before use to form a clear, colourless solution.

Ingredients

Miochol-E contains 20 mg of acetylcholine chloride as the active ingredient. It also contains:

- mannitol
- sodium acetate
- · magnesium chloride
- potassium chloride
- calcium chloride
- · water for injections.

Sponsor

In Australia, Miochol-E is supplied by:

Bausch & Lomb (Australia) Pty Ltd Chatswood, NSW 2067 Phone: 1800 251 150

In New Zealand, Miochol-E is supplied by:

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

48 Shortland Street Auckland 1140