1.3.2 Patient Information Leaflet

SCHEDULING STATUS: S3

MIOCHOL-E

Lyophilized powder and solvent for instillation solution for intraocular use

Acetycholine chloride 20 mg/ml

Read all of this leaflet carefully before you start using MIOCHOL-E

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- MIOCHOL-E has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MIOCHOL-E is and what it is used for

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

2. What you need to know before you use MIOCHOL-E

You should not be administered MIOCHOL-E:

- if you are hypersensitive (allergic) to acetylcholine chloride or any of the other ingredients of MIOCHOL-E (listed in section 6).
- if you are a child.

Tell your doctor or healthcare professional before being given the injection if:

- You have any obstructions to your intestines or urinary tract
- You have asthma or other conditions that cause difficulty in breathing
- You have any heart diseases, including slow heart beat or if you recently suffered a heart attack
- You have problems with your nervous system (vagotonia)
- You suffer from epilepsy
- You have parkinsonism
- You have an overactive thyroid
- You have a stomach ulcer
- You are pregnant

Other medicines and MIOCHOL-E

Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines).

Medicines that break down the enzyme cholinesterase in the body may prolong and enhance the effect of MIOCHOL-E. These medicines are usually used for the treatment of myasthenia gravis.

When MIOCHOL-E is used with beta blockers (medicines used to treat heart conditions,

blood pressure, anxiety, glaucoma and migraine), it may lead to breathing problems.

MIOCHOL-E might be ineffective when used with anti-inflammatory medicines (NSAIDS).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before being given MIOCHOL-E.

The safety of using MIOCHOL-E during pregnancy or while breastfeeding has not been determined.

3. How to receive MIOCHOL-E

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself MIOCHOL-E. It will be given to you by a person who is qualified to do so.

During eye surgery, your healthcare professional will prepare the MIOCHOL-E solution immediately before use. The doctor or healthcare professional will then administer the solution through a small tube into the front chamber of your eye.

If you are administered more MIOCHOL-E than you should

Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage your healthcare professional will manage the overdosage.

Your healthcare professional may need to give you an injection of atropine sulphate or epinephrine (adrenaline).

4. Possible side effects

MIOCHOL-E can have side effects.

Not all side effects reported for MIOCHOL-E are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor if you notice any of the following:

Less frequent:

- abnormal vision or pain and discomfort in the eye
- slow heart rate
- dizziness or light-headedness due to low blood pressure
- flushing or sweating
- breathing difficulties

Frequency unknown:

- stomach pains, nausea (feeling sick) and vomiting
- excessive saliva or tears
- a runny nose
- burping
- diarrhoea
- frequent urination
- headache

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side

effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

or directly to the company, using the following e-mail address: PV-SouthAfrica@bauschhealth.com

By reporting side effects, you can help provide more information on the safety of MIOCHOL-E.

5. How to store MIOCHOL-E

MIOCHOL-E will be stored by your doctor.

Store all medicines out of reach of children.

The product should be stored at or below 25 °C and should not be frozen.

You should not be administered MIOCHOL-E after the expiry date printed on the pack.

6. Contents of the pack and other information

What MIOCHOL-E contains

Each vial contains:

- The active substance is acetycholine chloride 20 mg.
- The inactive ingredient is mannitol.

Each ampoule contains:

- The inactive ingredients are: calcium chloride dihydrate, magnesium chloride hexahydrate, potassium chloride hexahydrate, potassium chloride, sodium acetate trihydrate and water for injection.

What MIOCHOL-E looks like and contents of the pack

Contents of vial: White solid lyophilisate or powder, free from visible foreign particles.

Contents of ampoule: Clear, colourless solution.

The reconstituted preparation is a clear, colourless solution.

MIOCHOL-E is provided in cardboard carton packs containing a patient information leaflet and 1 blister and 1 filter hub, or 12 blisters and 12 filter hubs, respectively.

One blister contains:

- vial containing powder: clear, colourless type I glass with rubber stopper and aluminium cap with a plastic cover
- ampoule containing solvent: clear colourless type I glass ampoule with a One Point Cut (OPC).
- Filter hub with 5 micron filter, luer lock (CE marking number: CE0123)

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The Professional Information is available on the company website, www.bausch.co.za, or may be requested telephonically: +27 10 025 2100.