DILUENT FOR MIOCHOL E
PL 00101/0723

UKPAR

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DILUENT FOR MIOCHOL E
PL 00101/0723

LAY SUMMARY

The MHRA today granted Novartis Pharmaceuticals UK Ltd a Marketing Authorisation (licences) for the medicinal product Diluent For Miochol E (PL 00101/0723). This product is a prescription only medicine and contains water for injections for use as a diluent for Miochol E in intra-ocular treatment.

No new or unexpected safety concerns arose from this application and it was therefore judged that the benefits of using Diluent For Miochol E outweigh the risks, hence a Marketing Authorisation has been granted.

DILUENT FOR MIOCHOL E
PL 00101/0723

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy the UK granted a marketing authorisation for the medicinal product Diluent for Miochol E to Novartis Pharmaceuticals UK Ltd (PL 00101/0723) on 12th January 2006. The product is prescription only.

The application was submitted as an abridged application according to Article 10.3 of Directive 2001/83/EC. The original product for this application was Miochol E (PL 00101/0607), which was licensed to Novartis Pharmaceuticals UK Limited on 26th December 1999. The original product was supplied as a two-chambered vial (univial), one chamber containing the drug substance and the other the diluent. This current application is for the diluent only.

The product contains a buffered, electrolyte solution of water for injections and is to be used as a diluent for Miochol E in intra-ocular treatment.

The product is used as a solvent for reconstitution of Miochol E 20 mg powder for intraocular solution and has been formulated to be physiologically compatible with the eye - it is an electrolyte solution designed to mimic the aqueous humor. The presentation of this product is as an ampoule as opposed to the upper chamber of a univial that was used for the originator product (PL 00101/0607) and as such requires a separate marketing authorisation.

PHARMACEUTICAL ASSESSMENT

ACTIVE SUBSTANCE

General information

The product contains water for injections and is to be used as a diluent for Miochol E in intra-ocular treatment. Synthesis of water for injections has been adequately described and appropriate in-process controls are applied. The proposed specification for water for injections complies with the monograph in the European Pharmacopoiea. Batch analysis data are provided and comply with the proposed specification. No excipients of animal or human origin have been used in the production of water for injections.

DRUG PRODUCT

Composition

The product is to be used as the solvent for Miochol E 20mg powder for intraocular solution. Ingredients include sodium acetate trihydrate, potassium chloride, magnesium chloride hexahydrate, calcium chloride dehydrate and water for injections.

Pharmaceutical Development

Formulation development

The product has been formulated to be physiologically compatible with the eye and to minimise impact of surgical intrusion on the corneal endothelial cells. The product is an electrolyte solution designed to mimic the natural fluid within the aqueous humour of the eye. The product contains the four major cations present in the aqueous and viterous humor, Na^+, K^+, Mg^+ and Ca^{2+}, at concentrations within the normal range of these ions. A number of literature sources have been sited which state that these ions with chloride ions have a protective effect on the corneal endothelial cells. The osmolality of the reconstituted solution makes it isotonic with the aqueous humor.

The formulation consists of a powder and a solvent for reconstitution. This product is the solvent for reconstitution. The original formulation, Miochol, used water for injections in an upper chamber of a univial as the solvent for reconstitution. This was then replaced by the current buffered electrolyte solution, Miochol E, which used sodium acetate and other electrolytes to control pH, improve overall product stability and improve physiological compatibility with the eye.

This product contains the same buffered electrolyte system as the current product but changes the presentation to an ampoule rather than the upper chamber of the univial.

Physiological and biological properties

The pH and ionic strength of the reconstituted solution have been chosen to mimic the physiological conditions of the eye. Rapid use is emphasised to minimise the degradation products formed.

Manufacturing development

The manufacturing process for the solvents is considered to be standard as it only consists of dissolving inorganic salts in water for injections.

Manufacture

Manufacturer(s)
Satisfactory manufacturers' licences have been provided for all manufacturers involved in the production of this product.

A flow diagram detailing the manufacturing process and in-process control testing has been provided. A written summary of the process has been included. The in-process controls are suitable and specifications reasonable for this type of product.

The manufacturing method for the sterilisation of the product has been adequately validated using production-scale batches produced in the same production facility, and the same equipment and process as that intended for marketing.

The production of the solution has been shown to be reproducible.

Control of excipients
Specification
Sodium acetate trihydrate, potassium chloride, magnesium chloride hexahydrate, and calcium chloride dihydrate have monographs in the European Pharmacopoeia. A certificate of analysis from one batch of each has been provided from the finished product manufacturer, which is in compliance with the respective monographs. The testing includes additional microbiological and endotoxin tests for each of the excipients.

The analytical methods used to test the excipients are those provided in the European Pharmacopoeia. Consequently no validation data has been supplied.

No excipients of human or animal origin have been used in the manufacture of the finished product.

Control of drug product
Specification
The finished product specifications proposed for both release and shelf life are acceptable and provide an assurance of the quality and consistency of the finished product. The analytical methods used have been suitably validated. Batch analysis data have demonstrated compliance with the proposed release specification.

Analytical procedures
All the details have been provided for the pharmacopoeial and non-pharmacopoeial methods.

Validation
The identification tests have been validated on specificity with acceptable results in relation to each component from control and placebo solutions.

The assay for total chlorides by titration has also been validated. The method is accurate and precise. Linearity has been demonstrated satisfactorily.

Details have been provided for the endotoxin method validation. These are satisfactory.

Sterility validation data has been provided for the finished product and the external surfaces with both in compliance with the requirements of the European Pharmacopoeia.

Reference standards
Relevant information on the reference standards has been provided.

Batch analyses
Batch analyses have been provided for commercial scale batches. All batches comply with the proposed specification.

Container closure system
The product is presented as a clear and colourless solution packed in a 2ml ampoule of colourless borosilicate glass, type I with a one point cut (OPC) opening system

Sorption of the electrolyte excipients to the glass can be excluded. The solution is not basic and does not contain metal-complexing components so studies on leaching of ions is not considered necessary.

The primary packaging meets the requirements of the European Pharmacopoeia. All tests performed on the packaging by either the finished product manufacturer or packaging supplier are satisfactory. Batch analyses of the packaging used for marketing have been provided demonstrating compliance to the specification.

Stability
Stability has been determined on validation batches produced at the commercial scale. These data support a shelf life of 24 months (unopened), and 6 months after opening or reconstitution, with storage conditions “Avoid freezing. Do not store above 25°C”

SPC, PIL, Labels
The SPC and Labels are pharmaceutically acceptable. No PIL has been provided for this product, which is acceptable given that this product is to be used as a diluent for Miochol E (which does have an appropriate PIL).

CONCLUSION
It is recommended that a Marketing Authorisation is granted for this application.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

This product is identical in formulation to that already contained in the univial used as the solvent for the existing product that has a marketing authorisation. An application has been submitted for a new authorisation as it is intended that the solvent will now be packaged in a separate ampoule. As the pharmaceutical assessor is satisfied with the overall quality of the formulation and packaging, there is no reason to believe that the risk benefit ratio be any different from that of the existing product.

The SPC is acceptable. No PIL has been provided for this product, which is acceptable given that this product is to be used as a diluent for Miochol E (which does have an appropriate PIL). The labelling is clinically satisfactory.

As it is not envisaged that the change to the container will affect the efficacy and safety of the product, no new efficacy or safety data have been presented.

CONCLUSION
It is recommended that a Marketing Authorisation is granted for this application.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The important quality characteristics of Diluent for Miochol E are well defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL

No new preclinical data were submitted and none are required for applications of this type.

EFFICACY

No new or unexpected safety concerns arise from this application.

The SPC and labelling are satisfactory.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The risk benefit is therefore considered to be positive.

DILUENT FOR MIOCHOL E
PL 00101/0723

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation application on 28th January 2005
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 14th March 2005
3	Following assessment of the application the MHRA requested further information relating to the quality dossier on 29th July, 24th August and 29th November 2005
4	The applicant responded to the MHRA's requests, providing further information on 1st August 2005, 29th November 2005 and 11th January 2006.
5	The application was determined on 12th January 2006

DILUENT FOR MIOCHOL E
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STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

1. NAME OF THE MEDICINAL PRODUCT

Diluent for Miochol E

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule contains 99.77% water for injection.

For excipients see 6.1.

3. PHARMACEUTICAL FORM

Solvent for use with Miochol-E 20mg powder for solution for intraocular irrigation. Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

None

4.2. Posology and method of administration

For intraocular use.

Diluent for Miochol-E is given for intraocular use, after reconstitution.

4.3. Contraindications

Not Applicable

4.4. Special warnings and precautions for use

This medicine contains potassium, less than 1mmol (39mg) per 2ml dose. This medicine contains less than 1 mmol sodium (23mg) per 2ml dose.

4.5. Interactions with other medicinal products and other forms of interaction

Not Applicable

4.6. Pregnancy and lactation

Not Applicable

4.7. Effects on ability to drive and use machines

Not Applicable

4.8. Undesirable effects

Not Applicable

4.9. Overdose

Not Applicable

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: solvents and diluting agents inc irrigation solutions, ATC code: V07AB

5.2. Pharmacokinetic properties
Not Applicable

5.3. Preclinical safety data
Each of the constituents are well established pharmacopoeial ingredients, so no further information is presented.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
Calcium chloride dihydrate, magnesium chloride hexahydrate, potassium chloride, sodium acetate trihydrate.

6.2. Incompatibilities
Not Applicable

6.3. Shelf life
2 years

Following reconstitution with Miochol-E: 6 hours

6.4. Special precautions for storage
No special precautions for storage.

Chemical and physical in-use stability has been demonstrated for 6 hours at 2-8 ◦C or for 6 hours at 25 ◦C

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would not normally be longer than 6 hours at 2-8 ◦C or 6 hours at 25 ◦C.

6.5. Nature and contents of container
Type 1 clear glass ampoule with filter.

6.6. Instruction for use and handling and disposal
See Summary of Product Characteristics for Miochol E

7. MARKETING AUTHORISATION HOLDER
Novartis Pharmaceuticals UK Ltd
Frimley Business Park,
Frimley,
Surrey,
GU16 7SR,
United Kingdom

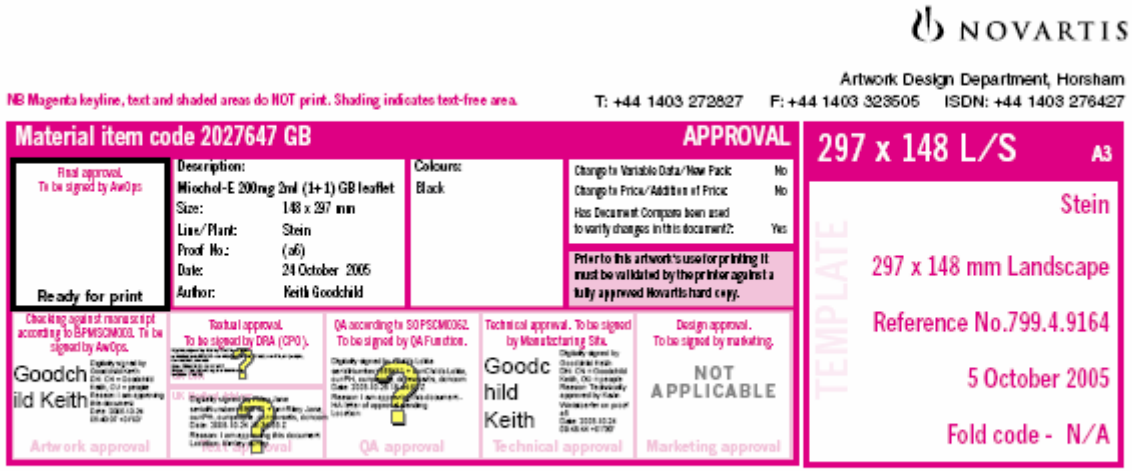
8. MARKETING AUTHORISATION NUMBER
PL 00101/0723

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/01/2006

10 DATE OF REVISION OF THE TEXT

12/01/2006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Artwork Design Department, Horsham
NB Magenta keyline, text and shaded areas do NOT print. Shading indicates text-free area.
T: +44 1403 272827 F: +44 1403 323505 ISDN: +44 1403 276427
Material item code 2027647 GB
APPROVAL
297 x 148 L/S
A3
Final approval. To be signed by AwOps
Ready for print
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Size: 148 x 297 mm
Line/Plant: Stein
Proof No.: (a6)
Date: 24 October 2005
Author: Keith Goodchild
Colours:
Black
Change to Variable Data/New Pack: No
Change to Price/Addition of Price: No
Has Document Compare been used to verify changes in this document?: Yes
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Technical approval. To be signed by Manufacturing Site.
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Technical approval
Design approval. To be signed by marketing.
NOT APPLICABLE
Marketing approval
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Stein
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Reference No.799.4.9164
5 October 2005
Fold code - N/A

NOVARTIS

MIOCHOL-E®

20 mg, powder and solvent for solution for intraocular irrigation

(Acetylcholine chloride)

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you are given this medicine.
Keep this leaflet. You may need to read it again.
If you have further questions, please ask your doctor or your pharmacist.
This medicine has been prescribed for you personally and you should not pass it on to others.
It may harm them, even if their symptoms are the same as yours.

IN THIS LEAFLET

MIOCHOL-E, 20 MG, POWDER AND SOLVENT FOR SOLUTION FOR INTRAOCULAR IRRIGATION

The active substance in Miochol-E is acetylcholine chloride. It is supplied as a powder for reconstitution in a vial. Each pack contains the vial of powder and an ampoule of solvent. One vial contains 20 mg of acetylcholine chloride. Each ampoule contains 2 ml of solvent.

The other ingredients of the vial are mannitol. The other ingredients of the ampoule are sodium acetate trihydrate, magnesium chloride hexahydrate, potassium chloride, calcium chloride dihydrate and water for injection.

MARKETING AUTHORISATION HOLDER

Novartis Pharmaceuticals UK Limited
Frimley Business Park
Frimley
Camberley
Surrey
GU16 7SR
United Kingdom

MANUFACTURER RESPONSIBLE FOR RELEASE ONTO THE MARKET

Novartis Pharmaceuticals UK Ltd
Wimblehurst Road
Horsham
West Sussex
RH12 5AB
United Kingdom

1. WHAT MIOCHOL-E IS AND WHAT IT IS USED FOR

Miochol-E is used during cataract surgery and other types of eye surgery. It is used to make the pupil (at the front of the eye) contract. This helps the surgeon carry out the surgical procedure.

Acetylcholine chloride belongs to a group of substances called parasympathomimetics (neurohormones). It is involved with the transmission of nerve impulses in the body.

Miochol-E and diluent for Miochol-E comes in a blister pack containing one vial of Miochol-E and one ampoule of solvent. Each vial contains 20 mg of acetylcholine chloride. Each ampoule contains 2 ml of solvent.

Miochol-E is supplied in packs containing 1 vial and 1 ampoule. The Miochol-E powder requires reconstitution with the solvent before it is given for intraocular use (i.e. use in the eye). Reconstituted it contains 10 mg/ml of acetylcholine chloride (20 mg/2 ml). The reconstituted solution is a clear, colourless solution.

If you have any questions about how Miochol-E works or why this medicine has been prescribed for you, ask your doctor or pharmacist.

It is available only for hospital use.

NOTE: This is a patient information leaflet. Doctors and other health professionals involved in the administration of Miochol-E should consult the Summary of Product Characteristics (SPC) and the administration instructions for Healthcare Professionals section of this leaflet before use.

2. BEFORE YOU ARE GIVEN MIOCHOL-E

Follow carefully the instructions given to you by your doctor.

You must not be given Miochol-E:

If you are allergic (hypersensitive) to acetylcholine chloride or to any of the ingredients of Miochol-E listed at the beginning 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.

Take special care with Miochol-E:

If the answer to any of the following questions is 'yes', talk to your doctor or pharmacist before you are given Miochol-E:

- Are taking or have you recently taken non-steroidal anti-inflammatory agents (used to treat pain and swelling).

In cataract surgery the surgeon should only use Miochol-E only after placement of the intraocular lens.

NOVARTIS

MIOCHOL-E®

20 mg, powder and solvent for solution for intraocular irrigation

(Acetylcholine chloride)

INFORMATION FOR THE HEALTHCARE PROFESSIONAL

Warning: Do not use if blister or peelable backing is damaged or broken. Open under aseptic conditions only.

How to prepare Miochol-E

1. Inspect unopened blister to ensure that it is intact. Peel open blister.
2. Aseptically transfer the ampoule, vial and filter hub to sterile field. Maintain asepsis during preparation of the solution.
3. Aseptically attach a sterile 18 to 20 gauge, bevelled needle to the luer tip of a sterile disposable syringe with twisting motion to assure a secure fit.
4. Break open the ampoule containing the solvent. The One Point Cut (OPC) ampoule must be opened as follows: Hold the bottom part of the ampoule with the thumb pointing to the coloured point. Grasp the top of the ampoule with the other hand, positioning the thumb at the coloured point and press back to break at the existing cut under the point.
5. Remove the needle protector and withdraw the solvent from the ampoule into the syringe. Discard ampoule.
6. Remove and discard the plastic cap from the top of vial.
7. Insert the needle through the centre of the vial stopper.
8. Transfer the solvent from the syringe to the vial.
9. Shake gently to dissolve drug.
10. Slowly withdraw the solution from the vial through the needle into the syringe.
11. Discard needle.
12. Aseptically open the filter hub pouch.
13. Aseptically attach the filter hub onto luer tip of syringe with a twisting motion to assure secure fit.
14. Aseptically attach a sterile blunt tip irrigation cannula to male luer of filter prior to intraocular irrigation.
15. Discard appropriately after use. Do not re-use the filter hub.

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The solution must be mixed just before use, since aqueous solutions of acetylcholine are unstable. Only clear and colourless solutions should be used.

Miochol-E should not be re-sterilised. The filter hub is recommended only for use with Miochol-E.

Aspiration through the filter is not recommended. However, if utilised, discard needle and syringe filter to prevent recontamination of fluids during injection. Do not aspirate and inject through the same filter.

Do not use unless a clear and colourless solution is produced.

For single use only. Discard any unused solution.

How to store Miochol-E

- Do not store Miochol-E above 25°C. Do not freeze.
- Do not use Miochol-E after the expiry date printed on the box.
- Do not use any Miochol-E pack that is damaged or shows signs of tampering.
- Keep Miochol-E out of the reach and sight of children.

Revision date: September 2005

Miochol-E and older people

Miochol-E can be given to older people.

Miochol-E in children

The use of Miochol-E in children has not been studied and therefore is not recommended.

Pregnancy and Breast-feeding

Tell your doctor if you are or think you may be pregnant. Tell your doctor if you are breastfeeding. The doctor will discuss with you the risks and benefits involved.

Driving and using machines:

The drug, but above all the surgical procedure, may impair vision. Patients should not drive or use machines until such disturbances have subsided.

Important information about some of the ingredients of Miochol-E

This medicine contains potassium, less than 1 mmol (39 mg) per 2 ml dose. This medicine contains less than 1 mmol sodium (23 mg) per 2 ml dose.

Taking other medicines:

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those you have bought without a prescription.

In particular, you should inform your doctor if you are taking any of the following:

- Topical non-steroidal anti-inflammatory agents (used to treat pain and swelling).

3. HOW MIOCHOL-E IS GIVEN

Follow carefully all instructions given to you by your doctor.

How much is given

Your surgeon will work out the correct dose of Miochol-E for you. In most cases 0.5 ml to 2 ml is a suitable dose.

How Miochol-E is given

Miochol-E is applied drop by drop into the area behind the eye during surgery. The solution should be made up just before it is needed. Each vial of Miochol-E and solvent is for single use only.

When Miochol-E is given

Your surgeon will determine when you will be given Miochol-E. In cataract surgery Miochol-E should only be used after the replacement lens has been inserted into the eye.

If too much Miochol-E is given

If you are given more Miochol-E than you need, your doctor may need to give you an injection of either atropine sulphate or adrenaline to control symptoms. Symptoms of overdose may include slow heart rate, too low blood pressure, flushing, breathing difficulties and sweating. Because acetylcholine is rapidly broken down by the body symptoms of overdose are unlikely to occur.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Miochol-E can have side effects, even when used as directed.

Uncommonly, the cornea (window of the eye) has become cloudy with use of intraocular acetylcholine.

The following symptoms have been reported rarely while taking intraocular acetylcholine:

slow heart rate, dizziness or light-headedness due to low blood pressure, flushing, breathing difficulties, sweating and abnormal vision due to a problem related to the cornea (the front of the eyeball).

If any of these affects you, tell your doctor. If you notice any other side effects not mentioned in this leaflet, please inform your doctor.

5. STORING MIOCHOL-E

- Do not store Miochol-E above 25°C. Do not freeze.
- Do not use Miochol-E after the expiry date printed on the box.
- Do not use any Miochol-E pack that is damaged or shows signs of tampering.
- Keep Miochol-E out of the reach and sight of children.

6. FURTHER INFORMATION

Syringe Filter CE 0120 the filter conforms with Directive 93/42/EEC.

Leaflet revised: September 2005

Miochol-E® is a registered trademark

® Registered Trademark

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EXP/LOT:
Miochol®-E 20 mg
Acetylcholine chloride
50x30x105
Miochol®-E 20 mg
Acetylcholine chloride
Powder and Solvent for Solution
for intraocular irrigation
Composition:
Each vial contains: acetylcholine chloride 20 mg (10 mg/mL) and mannitol 56 mg.
Each ampoule contains 2 mL of modified solvent of sodium acetate trihydrate (E 262), potassium chloride (E 508), magnesium chloride hexahydrate (E 511), calcium chloride dihydrate (E 509) and water for injection (for ophthalmic use).
Do not use unless a clear and colourless solution is produced.
For single use only.
Discard any unused solution.
See package leaflet for handling and instructions for reconstitution.
Syringe filter
CE 0123
5 010678 913170
Do not store above 25°C.
Do not freeze.
Keep out of reach and sight of children.
See package insert for additional information before use.
To be used as directed by a doctor.
For intraocular use.
Miochol-E provides 10 mg/ml of acetylcholine chloride when diluted as recommended.
PL 00101/0609
PL 00101/0723
PA 13/103/2
POM
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Miochol®-E 20 mg
Acetylcholine chloride
Powder and Solvent for Solution
for intraocular irrigation
For intraocular irrigation only
STERILE EO
Sterilisation with ethylene oxide
Contains Miochol®-E 20 mg powder for intraocular irrigation and diluent for Miochol®-E 2 mL
One syringe filter
NOVARTIS
Miochol®-E 20 mg
Acetylcholine chloride
Powder and Solvent for Solution
for intraocular irrigation
Novartis
Pharmaceuticals UK Limited
Frimley Business Park
Frimley, Camberley
Surrey, GU16 7SR
Miochol®-E 20 mg
Acetylcholine chloride
Powder and Solvent for Solution
for intraocular irrigation
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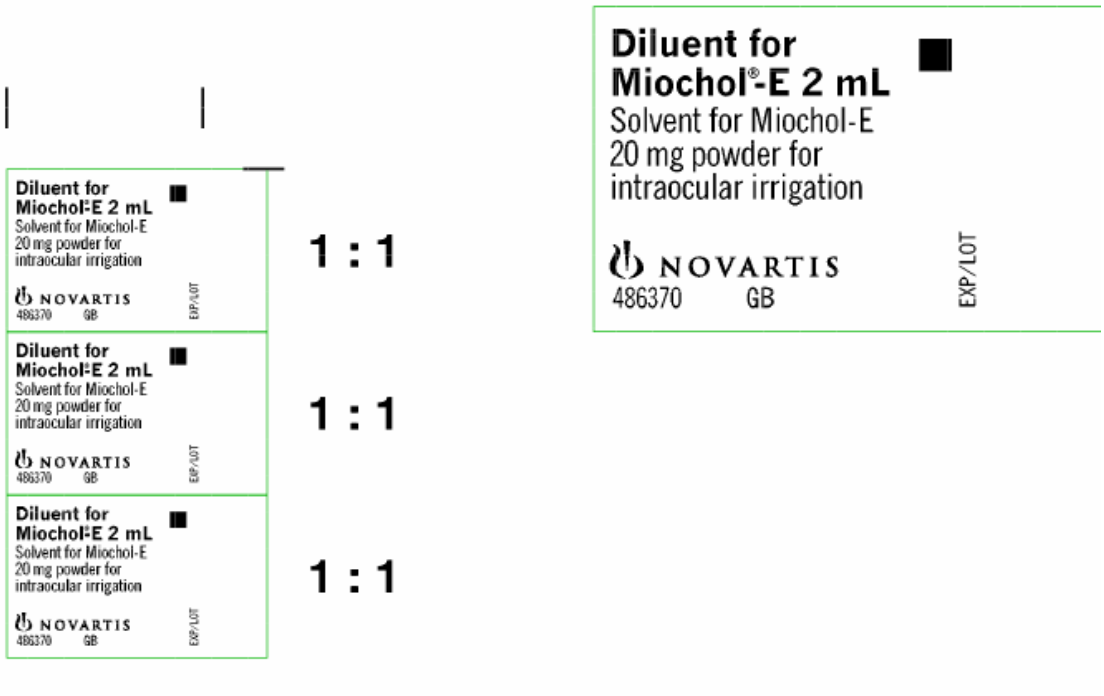
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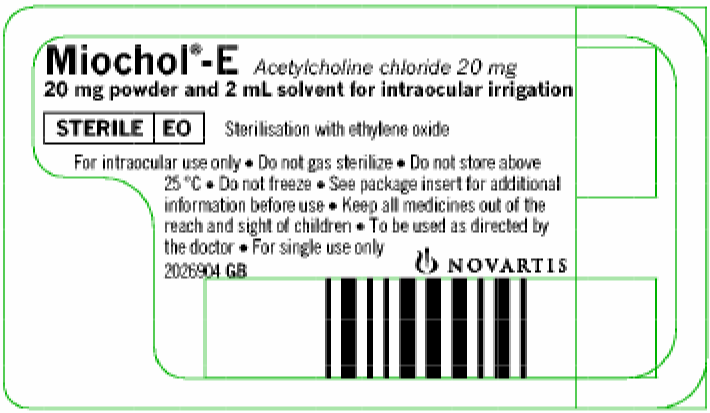
Miochol®-E Acetylcholine chloride 20 mg
20 mg powder and 2 mL solvent for intraocular irrigation
STERILE EO Sterilisation with ethylene oxide
For intraocular use only • Do not gas sterilize • Do not store above 25 °C • Do not freeze • See package insert for additional information before use • Keep all medicines out of the reach and sight of children • To be used as directed by the doctor • For single use only
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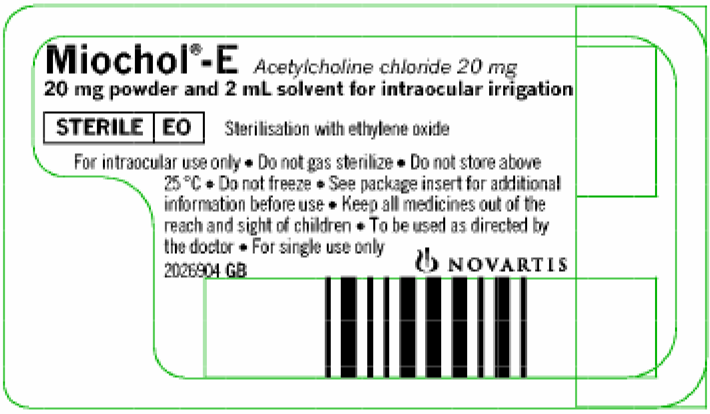
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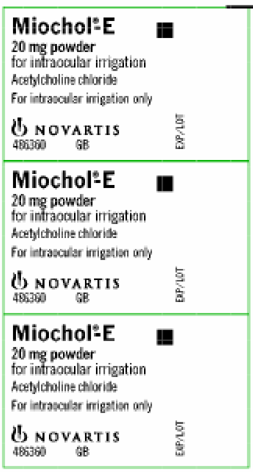
Miochol®-E
20 mg powder
for intraocular irrigation
Acetylcholine chloride
For intraocular irrigation only
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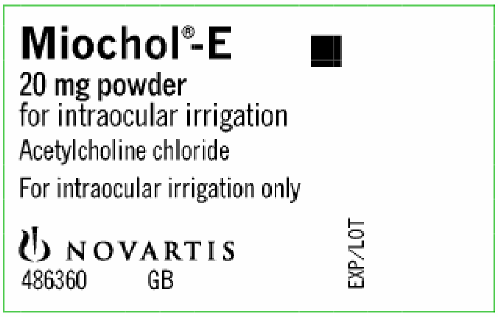
Miochol®-E
20 mg powder
for intraocular irrigation
Acetylcholine chloride
For intraocular irrigation only
NOVARTIS
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EXP/LOT