HYPROMELLOSE EYE DROPS BPC 0.3%
PL 00156/0124

UKPAR

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PL 00156/0124

LAY SUMMARY

The MHRA granted Martindale Pharmaceuticals Limited a Marketing Authorisation for the medicinal product Hypromellose Eye Drops BPC 0.3% (PL 00156/0124) on 19th February 2009. This is a pharmacy [P] medicine used to treat conditions where not enough tears are made to keep the eye lubricated and clean. Hypromellose Eye Drops lubricate the surface of the eye in the same way as natural tears. It cane therefore be used to relieve the dryness and pain associated with reduced or abnormal tear production.

The physical characteristics of hypromellose eye drops are similar to those of natural tears, providing lubrication to the surface of the eye.

This application is identical to a previously granted application for Hypromellose Eye Drops BPC 0.3% (PL 00156/0069), held by the same Marketing Authorisation Holder, granted 6th June 1997 as a change of ownership.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Hypromellose Eye Drops BPC 0.3% outweigh the risks; hence a Marketing Authorisation has been granted.

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Hypromellose Eye Drops BPC 0.3% (PL 00156/0124) to Martindale Pharmaceuticals Limited on 19th February 2009. The product is a pharmacy medicine.

The application was submitted as a simple abridged application according to Article 10c of Directive 2001/83/EC, cross-referring to Hypromellose Eye Drops BPC 0.3% (Martindale Pharmaceuticals Limited, PL 00156/0069), approved on 6th June 1997 as a change of ownership.

No new data were submitted nor was it necessary for this simple application, as the data are identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report (PAR) has been generated for it.

The product contains the active ingredient hypromellose. The physical characteristics of the product are similar to those of natural tears, providing lubrication to the ocular surface and maintaining corneal hydration in dry eye syndromes.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 00156/0124
PROPRIETARY NAME: Hypromellose Eye Drops BPC 0.3%
ACTIVE(S): Hypromellose
COMPANY NAME: Martindale Pharmaceuticals Limted.
E.C. ARTICLE: Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC
LEGAL STATUS: P

1. INTRODUCTION

This is a simple, informed consent application for Hypromellose Eye Drops BPC 0.3% submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder is Martindale Pharmaceuticals Limited, Bampton Road, Harold Hill, Essex, RM3 8UG, UK.

The application cross-refers to Hypromellose Eye Drops BPC 0.3%, approved on 6th June 1997 to the same marketing authorisation holder. The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Hypromellose Eye Drops BPC 0.3%. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The product contains hypromellose, equivalent to 0.3%w/v. It is to be stored in plastic tamper evident bottles with a fill volume of 10ml. The proposed shelf-life (36 months-unopened and 28 days after opening) and storage conditions ("Store below 25°C) are consistent with the details registered for the cross-reference product.

2.3 Legal status

On approval, the product will be available as a pharmacy medicine (P).

2.4 Marketing authorisation holder/Contact Persons/Company

Martindale Pharmaceuticals Limited, Bampton Road, Harold Hill, Essex, RM3 8UG, UK.

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in line with the details registered for the cross-reference product with the exception of an additional test for moisture.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
There are no excipients from sources of animal or human origin. Satisfactory TSE statement is provided.This is consistent with the cross-reference product.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS
The proposed summary is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET/CARTON
PIL
The patient information leaflet has been prepared in-line with the details registered for the cross-reference product.
The PIL is essentially the same with respect to content, layout and format as that of the reference product except for the PL number. The user tested PIL along with user testing data for the reference licence has been approved (PL00156/0069) and is therefore acceptable for the proposed product.

Carton and blister
The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS
The data submitted with the application are acceptable. A Marketing Authorisation should be granted.

PRECLINICAL ASSESSMENT

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

CLINICAL ASSESSMENT

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

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for this application is consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type.

EFFICACY
Hypromellose Eye Drops BPC 0.3% is a well known drug and has been used to provide tear-like lubrication for the symptomatic relief of dry eyes and eye irritation associated with deficient tear production for many years. This application is identical to previously granted application for Hypromellose Eye Drops BPC 0.3% (PL 00156/0069).

No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. Extensive clinical experience with hypromellose is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

HYPROMELLOSE EYE DROPS BPC 0.3%
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STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation application on 11th September 2008.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 15th September 2009.
3	The application was determined on 19th February 2009.

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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

HYPROMELLOSE EYE DROPS BPC 0.3%
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hypromellose Eye Drops BPC 0.3%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hypromellose BP (4500)

3 PHARMACEUTICAL FORM

Eye drops

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

To provide tear-like lubrication for the symptomatic relief of dry eyes and eye irritation associated with deficient tear production.

As an ocular lubricant for artificial eyes.

4.2 Posology and method of administration

Adults, children and the elderly

The dose depends on the need for lubrication. Usually one or two drops to each eye three times daily or as prescribed.

4.3 Contraindications

Hypersensitivity to any component.
Contains benzalkonium chloride, soft contact should not be worn.

4.4 Special warnings and precautions for use

If irritation persists or worsens, or headache, eye pain, vision changes or continuous redness occur, discontinue use and consult a physician.

Pharmacogenetic problems
None known.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

There is insufficient evidence of safety in pregnancy and this product should, therefore, only be used in pregnancy if it is considered essential by the physician.

4.7 Effects on ability to drive and use machines

May cause transient mild stinging or temporary blurring of vision.
Do not drive or operate machinery unless vision is clear.

4.8 Undesirable effects

May cause transient mild stinging or temporary blurring of vision.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

This product is a sterile, isotonic, buffered solution of Hypromellose. It is used as a substitute for natural tears.

5.2 Pharmacokinetic properties

Not appropriate.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water, Sodium Chloride, Potassium Chloride, Borax, Boric Acid, Benzalkonium Chloride solution and may contain sodium hydroxide or hydrochloric acid.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months unopened.
28 days after opening.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Plastic tamper evident eye drop assembly. Fill volume 10ml.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Martindale Pharmaceuticals Ltd.
Bampton Road,
Romford,
RM3 8UG
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00156/0124

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/02/2009

10 DATE OF REVISION OF THE TEXT

19/02/2009

11 DOSIMETRY (IF APPLICABLE)

Not Applicable

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

Not Applicable

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PATIENT INFORMATION LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER D00490

Hypromellose Eye Drops BPC 0.3%w/v

Hypromellose

(Referred to as Hypromellose Eye Drops in this leaflet)

Read all of this leaflet carefully before you start using this medicine. It contains important information.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Hypromellose Eye Drops are and what they are used for

The active ingredient hypromellose belongs to a group of medicines known as eye lubricants (ocular lubricants).

Hypromellose Eye Drops are used to treat conditions where not enough tears are made to keep the eye lubricated and clean. Hypromellose Eye Drops lubricate the surface of the eye (including artificial eyes) in the same way as natural tears. It can therefore be used to relieve the dryness and pain associated with reduced or abnormal tear production.

2. Before you use Hypromellose Eye Drops

Do not use Hypromellose Eye Drops if:
- you are allergic (hypersensitive) to Hypromellose or any of the other ingredients of this medicine, which are listed in section 6 of this leaflet.
- you are wearing soft contact lenses.

Take special care with Hypromellose Eye Drops if:
- your eye irritation persists or worsens,
- you have a headache or eye pain,
- your vision changes
- you have permanently red eyes

If any of the above apply to you, stop using Hypromellose Eye Drops and contact your doctor immediately.

If you are unsure about taking this medicine or you have any questions, go and talk to your doctor first and follow the advice given.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
You should not use Hypromellose Eye Drops if you are pregnant, trying for a baby or breast-feeding, unless your doctor believes it is necessary.

Driving and using machines
Hypromellose Eye Drops can cause mild stinging or blurring of vision after application. Wait until your vision is clear before driving or using machines.

Important information about some of the ingredients of Hypromellose Eye Drops
This medicine contains benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses.

Remove contact lenses before you use Hypromellose Eye Drops and wait at least 15 minutes before you put them back in.

3. How to use Hypromellose Eye Drops

Always use Hypromellose Eye Drops exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Soft contact lenses must not be worn during treatment with Hypromellose Eye Drops

Instructions for use
1. Before opening a new bottle of Hypromellose Eye Drops, please check that the safety strip on the front of the bottle is unbroken.
2. Tear off the safety strip to break the seal.
3. Wash your hands well before use.
4. Remove the outer cap. If you are putting in the drops yourself, you should use a mirror.
5. Tilt your head back and look up at the ceiling.
6. Pull the lower lid of the eye out to form a small pocket between your eyelid and your eye.
7. Hold the bottle between the thumb and middle finger of the other hand, turn the bottle upside down near to the eye, try not to touch the eye with the nozzle.
8. Apply enough pressure to the container to release one to two drops, as directed by your doctor.
9. Blink your eye a few times.
10. If you think that you have missed the eye, then insert another drop.
11. Repeat steps 5-10 for the other eye if you have been told to use Hypromellose Eye Drops in both eyes.
12. Replace the outer cap on the container, trying not to touch the applicator tip with anything, including the eye or your fingers.
13. Wash your hands

Continued overleaf

If you are unsure about how to use Hypromellose Eye Drops talk to your doctor or pharmacist.

How much to use
The usual dose is 1 or 2 drops placed in each eye three times daily, however this may vary depending on the amount of lubrication needed.

If there is no improvement see your doctor or pharmacist.

Hypromellose Eye Drops are for external use only.

If you use more Hypromellose Eye Drops than you should
It will not cause you any harm. If you are worried then talk to your doctor or pharmacist.

Hypromellose Eye Drops are for external use only. If you have swallowed or you suspect someone else has swallowed any of this medicine, contact your doctor.

If you forget to take Hypromellose Eye Drops
Don't worry, just take the next dose as soon as you remember and then go on as before. Do not take a double dose to make up for the one you have missed.

If you stop using Hypromellose Eye Drops
You should keep using Hypromellose Eye Drops for as long as your doctor has asked. Your treatment is helping your condition, even if you have not noticed a difference in how you feel. Should you need to stop your treatment, your doctor will advise you how to do this.

4. Possible side effects

Like all medicines, Hypromellose Eye Drops can cause side effects, although not everybody gets them.

Possible side effects include:
- temporary stinging or burning
- temporary blurring of vision

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Hypromellose Eye Drops

Keep out of the reach and sight of children.

Make sure the container is properly closed after each use.

Store below 25°C.

Do not use Hypromellose Eye Drops after the expiry date which is printed on the label. The expiry date refers to the last day of that month.

Dispose of this medicine four weeks after opening.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Hypromellose Eye Drops contain
The active substance is hypromellose BP 0.3%w/v
The other ingredients are purified water, sodium chloride, potassium chloride, borax, boric acid, benzalkonium chloride solution. It may also contain sodium hydroxide or hydrochloric acid.

What Hypromellose Eye Drops look like and contents of the pack
Hypromellose Eye Drops are a clear, colourless solution supplied in a plastic bottle with a dropper nozzle and a tamper proof cap. Each bottle contains 10ml of sterile solution.

Marketing Authorisation Holder and Manufacturer
Martindale Pharmaceuticals Ltd
Bampton Road, Harold Hill, Romford,
RM3 8UG, United Kingdom.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at the above address.

Product licence numbers:
Hypromellose Eye Drops BPC 0.3%w/v
PL 00156/0124

Leaflet approved: mm/yyyy
Date of revision: September 2008

MARTINDALE Pharmaceuticals

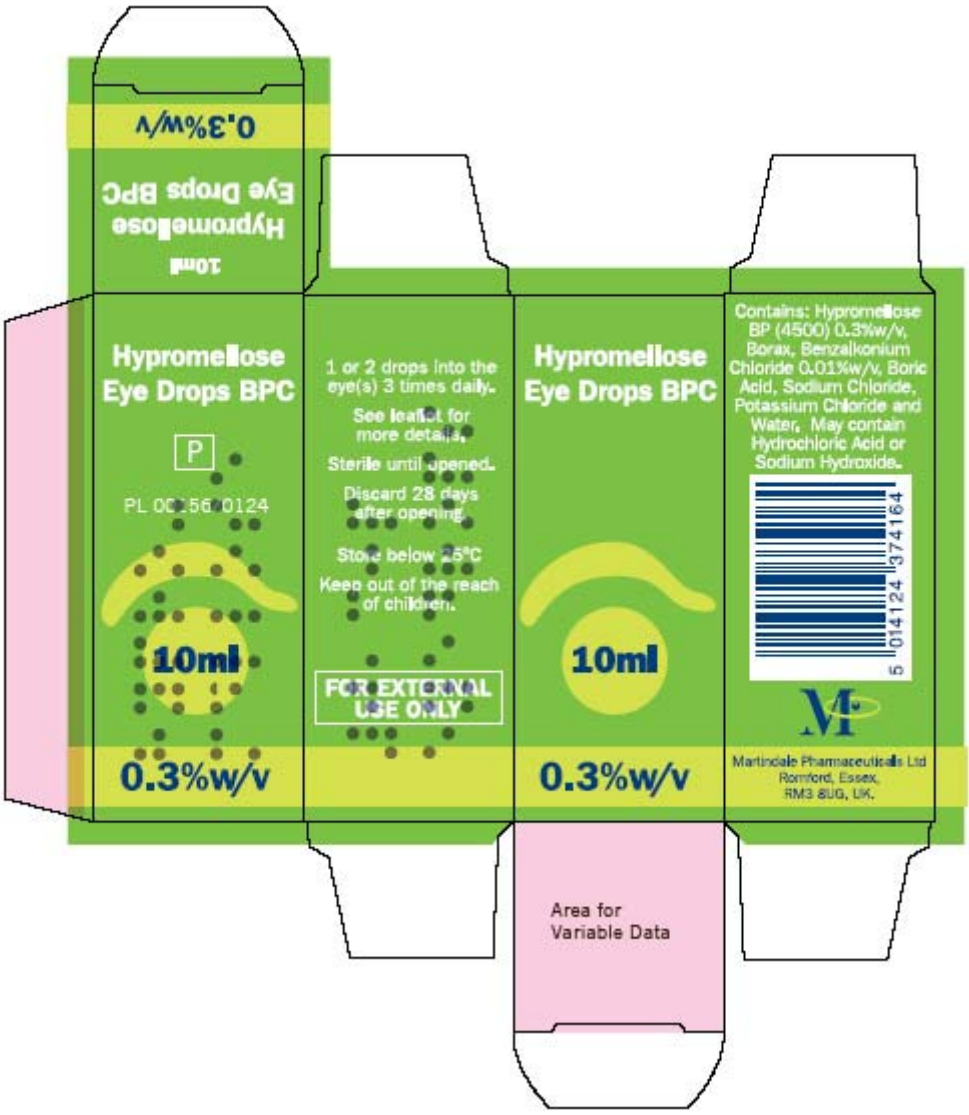
Bampton Road, Harold Hill
Romford, RM3 8UG
United Kingdom

D00490

HYPROMELLOSE EYE DROPS BPC 0.3%
PL 00156/0124

LABELLING

CARTON



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