Hypromellose Eye Drops BP 0.3% w/v

PL 23097/0006

UKPAR

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HYPROMELLOSE EYE DROPS BP 0.3% W/V

PL 23097/0006

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted a Marketing Authorisation (licence) for the medicinal product Hypromellose Eye Drops BP 0.3% w/v (product licence number: 23097/0006). These eye drops can only be bought from pharmacies.

Hypromellose Eye Drops BP 0.3% w/v is a soothing emollient solution used as artificial tears, it may be used:
- To help moisten hard contact lenses and to lubricate ocular prosthetics (artificial eyes).
- To prevent damage to the cornea when the ocular surface is not properly lubricated and covered by the eyelids.
- To provide relief from dry eye conditions (including those associated with the use of VDUs and TVs, infrequent blinking, certain medical treatments, atmospheric pollution and drying atmospheres, for instance, air conditioning, central heating, wind and sun).

Hypromellose Eye Drops BP 0.3% w/v raised no clinically significant safety concerns and it was, therefore, judged that the benefits of using this product outweigh the risks; hence a Marketing Authorisation has been granted.

HYPROMELLOSE EYE DROPS BP 0.3% W/V

PL 23097/0006

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 Hypromellose Eye Drops BP 0.3% w/v to The Swiss Group Ltd on 23 January 2009.

This is an abridged, simple application for Hypromellose Eye Drops BP 0.3% w/v submitted under Article 10(c) of EC Directive 2001/83, last paragraph. The applicant claims that this product is a generic version of Hypromellose Eye Drops BP (PL 15872/0005), which was licensed to FDC International Ltd on 16 January 1998. The reference product cross refers to Brolene Cool Eyes (PL 00109/0168), which was licensed to Roussel Laboratories Ltd on 25 July 1988.

No new data were submitted, nor was it necessary for this simple application, as the data are identical to those 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) was generated for it.

Hypromellose Eye Drops BP 0.3% w/v is used as artificial tears to prevent damage to the cornea in patients with kerato-conjunctivitis sicca accompanying rheumatoid arthritis, or keratitis or during gonioscopy procedures. It is also used to moisten hard contact lenses and to lubricate artificial eyes.

Hypromellose provides immediate relief from dry eye conditions (including dry eye conditions associated with the use of VDUs and TVs, infrequent blinking, certain medical treatments, atmospheric pollution and drying atmospheres, for instance, air-conditioning, central heating, wind and sun).

PHARMACEUTICAL ASSESSMENT

LETTERS OF ACCESS

A letter confirming that the applicant is in possession of the dossier for the reference product is provided.

The finished product manufacturer has provided written confirmation that they are prepared to manufacture the product on the applicant's behalf.

TSE

The applicant has declared that there are no materials of animal and/or human origin contained in, or used in the manufacturing process of, the medicinal product. This is in line with the reference product.

ADDITIONAL DATA REQUIREMENTS

The manufacturing processes, finished product specifications and active ingredient specifications are in line with the reference product and are satisfactory.

EXPERT REPORTS

Satisfactory expert reports in the form of quality, non-clinical and clinical overall summaries are provided, with signed declarations from each expert confirming that the applicant's product is identical to the reference product in all particulars. Expert CVs are also submitted and are acceptable.

PRODUCT LITERATURE

All product literature (SPCs, PILs and labelling) are satisfactory. The package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

ASSESSOR'S OVERALL CONCLUSIONS

A product licence may be granted for this product.

PRECLINICAL ASSESSMENT

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

CLINICAL ASSESSMENT

OVERVIEW

An appropriate clinical overview has been included in the dossier. The clinical overview contains a sufficient outline of the published literature concerning the clinical pharmacology, efficacy and safety of hypromellose.

BIOAVAILABILITY AND BIOEQUIVALENCE

No bioequivalence study has been performed to support this application and none is needed.

PRODUCT LITERATURE

All product literature (SPCs, PILs and labelling) are satisfactory. The package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

ASSESSOR'S OVERALL CONCLUSIONS

It is recommended that a marketing authorisation can be granted.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The important quality characteristics of Hypromellose Eye Drops BP 0.3% w/v 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

The efficacy of hypromellose is well established.

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, no significant preclinical or clinical safety concerns were identified, and benefit has been shown to be associated with Hypromellose Eye Drops BP 0.3% w/v. The risk benefit is therefore considered to be positive.

HYPROMELLOSE EYE DROPS BP 0.3% W/V

PL 23097/0006

STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application on 6 October 2005
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 6 October 2005
4	Following assessment of the application the MHRA requested further information relating to the quality dossier on 12 January 2006
5	The applicant responded to the MHRA's requests, providing further information on the quality dossier on 14 January 2007
6	Following assessment of the response the MHRA requested further information relating to the quality dossier on 29 March 2007
7	The applicant responded to the MHRA's requests, providing further information on the quality dossier on 22 April 2008
10	The application was determined on 23 January 2009

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hypromellose Eye Drops BP 0.3% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:	Hypromellose 0.3% w/v
Preservative:	Benzalkonium chloride 0.01% w/v

For other excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye Drops, Solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Hypromellose is used as artificial tears to prevent damage to the cornea in patients with kerato-conjunctivitis sicca accompanying rheumatoid arthritis, or keratitis or during gonioscopy procedures. It is also used to moisten hard contact lenses and to lubricate artificial eyes.

Hypromellose provides immediate relief of dry eye conditions (including dry eye conditions associated with the use of VDUs and TVs, infrequent blinking, certain medical treatments, atmospheric pollution and drying atmospheres eg air-conditioning, central heating, wind and sun.

4.2 Posology and method of administration

The recommended dosage for adults, children and infants of all age groups is one or two drops topically instilled into the eye three times daily as needed, or as directed by a physician.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

In order to help preserve sterility the dropper should not be allowed to touch the eyelids or any other surface. (Label warning: do not touch the eyelid with the dropper).

This formulation of Hypromellose Eye Drops contains benzalkonium chloride as a preservative. Benzalkonium chloride may be deposited in soft contact lenses and cause eye irritation and discoloration of the lenses. Hence, avoid contact with soft contact lenses. The lenses should be removed before instillation of the drops and not reinserted earlier than 15 minutes after use.

4.5 Interaction with other medicinal products and other forms of interaction
Hypromellose prolongs the contact time of topically applied drugs commonly used in ophthalmology.

4.6 Pregnancy and lactation
Safety for use in pregnancy and lactation has not been established. Therefore, use only when considered essential by the physician.

4.7 Effects on ability to drive and use machines
Not applicable to topical (ophthalmic) preparations. Hypromellose is not systemically absorbed..

4.8 Undesirable effects
If irritation persists or increases, use of drops should be discontinued.

4.9 Overdose
Not applicable to topical (ophthalmic) preparations. Hypromellose is not systemically absorbed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Hypromellose is a soothing emollient solution with properties and uses similar to those of methylcellulose. Its advantages over methylcellulose are that mucilages of hypromellose have greater clarity and fewer undispersed fibres are usually present. It prolongs the action of medicated eye drops and is used as artificial tears to prevent damage to the cornea in dry eye syndromes.
ATC Code: S01KA02 viscoelastic substances.

5.2 Pharmacokinetic properties
Not applicable to topical (ophthalmic) preparations. Hypromellose is not systemically absorbed.

5.3 Preclinical safety data
Nothing of relevance which is not included in other sections of the SPC

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Sodium chloride
Potassium chloride
Borax
Boric acid
Purified water
Sodium hydroxide solution (to adjust pH)
Hydrochloric acid (to adjust pH)

6.2 Incompatibilities

The product contains benzalkonium chloride and should not be used if soft contact lenses are worn.

6.3 Shelf life

Unopened: 24 months
Opened: 28 days

6.4 Special precautions for storage

Protect from light.
Do not store above 25ºC

6.5 Nature and contents of container

10ml polypropylene dropper bottle fitted with a low density polyethylene nozzle and a high density polyethylene tamper evident cap.

6.6 Special precautions for disposal

A slight haziness which may develop in the unopened product is normal and does not adversely affect the product. Discard within four weeks of opening

7 MARKETING AUTHORISATION HOLDER

The Swiss Group Ltd
235 Hunts Pond Road, Titchfield Common, PO14 4PJ
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 23097/0006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/01/2009

10 DATE OF REVISION OF THE TEXT

23/01/2009

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

HYPROMELLOSE EYE DROPS BP

Read all of this leaflet because it contains important information for you.

This medicine is available without prescription. However, you still need to use Hypromellose 0.3% w/v Eye Drops carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.

- Ask your pharmacist if you need more information or advice.

- You must contact a doctor if your symptoms worsen or do not improve

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

In this leaflet:

1. What Hypromellose 0.3% w/v Eye Drops are and what they are used for

Hypromellose 0.3% w/v Eye Drops are a soothing emollient solution used as artificial tears. It may be used to help moisten **hard** contact lenses and to lubricate ocular prosthetics (artificial eyes). It prevents damage to the cornea when the ocular surface is not properly lubricated and covered by the eyelids. Hypromellose 0.3% w/v provides relief of dry eye conditions (including those associated with the use of VDUs and TVs, infrequent blinking, certain medical treatments, atmospheric pollution and drying atmospheres, e.g. air conditioning, central heating, wind and sun).

2. Before you use Hypromellose 0.3% Eye Drops

Take special care with Hypromellose 0.3% w/v Eye Drops if you:

• are allergic/sensitive to any of the ingredients in this product,
• wear soft contact lenses,
• are pregnant or breast-feeding,
• are taking other medicines. Hypromellose may increase the time other medicines stay in the eye.

Please tell your doctor, if you are using this medicine and develop signs of irritation or sensitivity.

Taking other medicines

Please tell your doctor or pharmacist if you are applying any other type of eye drops or eye ointment before you start to use this medicine. Your medicine may affect their action and could alter their effect.

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

Pregnancy and breast-feeding
If you are pregnant or breast-feeding you should discuss this with your doctor before you start to apply the eye drops.

Driving and using machines
Do not drive or operate machines if you have blurred vision after using Hypromellose 0.3% w/v Eye Drops. You should wait until this clears before driving or using machines.

3. How to use Hypromellose 0.3% Eye Drops

Always use Hypromellose 0.3% w/v Eye Drops exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dose depends upon the need for lubrication. Usually 1-2 drops should be administrated into each eye three times daily, or as directed by your doctor. People who wear soft contact lenses should remove their lenses before putting in the drops and wait at least 15 minutes before re-inserting their lenses.

To help keep the contents sterile, do not allow the dropper to touch your eyelids, fingers or any other surface.

Throw away the unused contents of the bottle after 28 days from first opening it.

Overdose
There is no experience of an overdosage with Hypromellose Eye Drops which is unlikely when given as eyedrops. If you accidentally swallow them contact your doctor.

4. Possible side effects

Like all medicines, Hypromellose 0.3% w/v Eye Drops can cause side effects, although not everybody gets them.

Most of these side effects affect only the eye and may not last very long. If you have any severe or persistent side effect you should **stop using the drops and contact your doctor immediately**. Side effects include:
• stinging,
• blurring of vision,
• burning sensation.

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

5. How to store Hypromellose 0.3% Eye Drops

Keep out of the reach and sight of children.

Do not store at a temperature above 25 °C. Store in the original bottle to protect from light.

Keep the container tightly closed.

Discard the bottle 28 days after opening, even if there is solution remaining.

Do not use Hypromellose 0.3% w/v Eye Drops after the expiry date which is stated on the bottle and on the carton the bottle is packed in.

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 0.3% w/v Eye Drops contain
The active ingredient is Hypromellose 4000 0.3% w/v. This product also contains: Potassium Chloride, Sodium Chloride, Benzalkonium Chloride Solution, Borax, Boric Acid sodium hydroxide and hydrochloric acid as excipients.

What Hypromellose 0.3% w/v Eye Drops look like and contents of the pack
One bottle of Hypromellose 0.3% w/v Eye Drops contains 10 ml solution.

Marketing Authorisation Holder
The Swiss Group Ltd
235 Hunts Pond Road
Titchfield Common, Hants.
PO14 4PJ
UK

Manufacturer
TUBILUX PHARMA S.P.A
Via Costarica 20/22
00040 Pomezia (RM)
ITALY

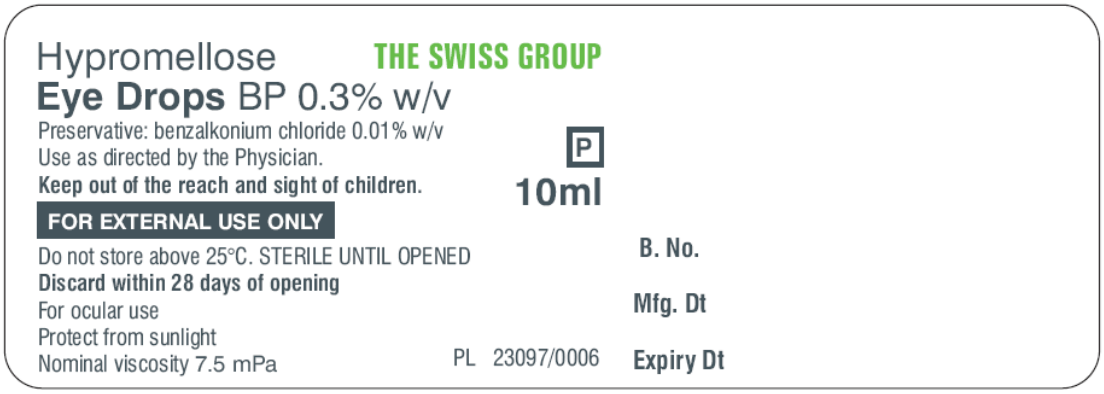
PL number 23097/0006

Hard to see or read the leaflet? Call 01489 574119 for help.

This leaflet was last approved in: xx/xxxx

LABELLING

Label:



Carton:


See enclosed leaflet for further information
FOR EXTERNAL USE ONLY
A slight haziness which may develop in unopened product is normal and does not adversely affect the product
Discard within 28 days of opening
One or two drops to be instilled into each eye up to three times daily or as directed by the Physician
Keep out of the reach and sight of children
Do not store above 25°C
Protect from light
Nominal Viscosity 7.5 mPa
STERILE UNTIL OPENED
Hypromellose
Eye Drops BP
0.3% w/v
10ml
FOR OCULAR USE
THE SWISS GROUP
Hypromellose Eye Drops BP 0.3% w/v
Preservative: benzalkonium chloride 0.01% w/v. Also contains sodium chloride, potassium chloride, borax, boric acid and purified water.
THIS PRODUCT CONTAINS BENZALKONIUM CHLORIDE AND SHOULD NOT BE USED IF SOFT CONTACT LENSES ARE BEING WORN
TO AVOID CONTAMINATION
DO NOT TOUCH DROPPER
TIP TO ANY SURFACE
MODE OF USE
SPIKE
Tighten the cap on the nozzle
The spike in the cap will pierce the lip of the vial
Dispense drops with gentle pressure
Replace the cap after every use
THE SWISS GROUP
Hypromellose
Eye Drops BP
0.3% w/v
10ml
Hypromellose Eye Drops
BP 0.3% w/v 10ml
PL Holder: THE SWISS GROUP LTD,
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P PL 23097/0006
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Mfg. Dt.
Expiry Dt.