Public Assessment Report

Hypromellose 0.3% w/v Eye Drops Single Dose Unit

Hypromellose

PL 11185/0006

Pharma Global Ltd

Table of Contents

<table>
<thead>
<tr>
<th>Table Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lay Summary</td>
<td>2</td>
</tr>
<tr>
<td>Scientific Discussion</td>
<td>3</td>
</tr>
<tr>
<td>Overall Conclusion And Risk Benefit/Analysis</td>
<td>6</td>
</tr>
<tr>
<td>Steps Taken During Assessment</td>
<td>7</td>
</tr>
<tr>
<td>Steps Taken After Assessment</td>
<td>8</td>
</tr>
<tr>
<td>Summary of Product Characteristics</td>
<td>9</td>
</tr>
<tr>
<td>Labels and Leaflet</td>
<td>14</td>
</tr>
</tbody>
</table>
Lay Summary

The MHRA granted a Marketing Authorisation for the medicinal product Hypromellose 0.3% w/v eye Drop Single Dose Unit (PL 11185/0006) to Pharma Global Ltd on 02/09/2009. The application was for a duplicate of the licence PL 11185/0002 Artelac 0.32% w/v Eye Drops Single Dose Unit held by Pharma Global Limited (the applicant).

Hypromellose acts as a lubricant and artificial tear in the symptomatic treatment of dehydration of the cornea and conjunctiva due to impaired lacrimal secretion and functional disorders as a result of topical or systemic diseases, or caused by deficient or incomplete eyelid closure.
Scientific Discussion

INTRODUCTION

The MHRA granted a marketing authorisation for the medicinal product Hypromellose 0.3% w/v eye Drop Single Dose Unit (PL 11185/0006) to Pharma Global Ltd on 02/09/2009. This was a simple abridged application under Article 10.c of Directive 2001/83/EC referring to the licence PL 11185/0002 Artelac 0.32% w/v Eye Drops Single Dose Unit held by Pharma Global Limited (the applicant).

The licence for Artelac 0.32% w/v Eye Drops Single Dose Unit (PL 11185/0002) held by Pharma Global Limited was granted as a change of ownership (CoA) on 25/01/2007 from Pharma Global (UK) Ltd to Pharma Global Limited. The original licence for Artelac Single Dose Unit (PL 02748/0016) was submitted under Article 10.1 (a) (iii) last paragraph with a different pharmaceutical form and strength to the reference product Isopto Plain (PL 00649/5920) licensed in the UK to Alcon in 1975.

Hypromellose acts as a lubricant and artificial tear in the symptomatic treatment of dehydration of the cornea and conjunctiva due to impaired lachrymal secretion and functional disorders as a result of topical or systemic diseases, or caused by deficient or incomplete eyelid closure.

It is suitable for use in adults and children. The normal dose is 1 drop instilled 3 to 5 times per day into the conjunctival sac or as required, to provide sufficient lubrication. Therapy for dry eye syndrome requires an individual dosage regimen.

ASSESSMENT

DRUG SUBSTANCE

The active ingredient in this product is identical to that in the reference product. Satisfactory letters of access have been provided. Drug substance specifications are identical to the reference product.

DRUG PRODUCT

Other Ingredients

The other ingredients in the product are Disodium phosphate dodecahydrate, Sodium dihydrogen phosphate dihydrate, Sorbitol E420 and Water for injections. These are identical to the reference product.

The manufacturing process and finished product specifications are identical to that of the reference product. The proposed compositions and references to Pharmacopoeial standards are identical to those registered for the reference products.
Container Closure System
The product is contained as a single dose in Low Density Polyethylene.

Stability
The product has a shelf-life of 2 years with the following storage condition “do not store above 25°C.

Product literature
A satisfactory Summary of Product Characteristics which was consistent with the reference product was provided. Satisfactory Patient Information Leaflet and labels were provided.

ASSESSOR’S OVERALL CONCLUSIONS ON QUALITY AND ADVICE
A Marketing Authorisation was granted.
PRE-CLINICAL AND MEDICAL ASSESSMENT

No clinical data or pre-clinical data were submitted with this application and none were required.
Overall Conclusion and Risk/Benefit Analysis

**Quality**
The quality aspects of the product were confirmed to be identical to the cross-reference product.

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

**Clinical**
The clinical aspects of the product were confirmed to be identical to the cross-reference product.

**Risk/Benefit Analysis**
The product was demonstrated to be identical to the cross-reference product which has already been found to have a positive risk/benefit ratio.
**Steps Taken During Assessment**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The MHRA received the application on 02/01/2008.</td>
</tr>
<tr>
<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 25/01/2008.</td>
</tr>
<tr>
<td>3</td>
<td>Following assessment of the application the MHRA requested further information from the applicant regarding the quality assessment on 28/03/2008 and 06/05/2009.</td>
</tr>
<tr>
<td>4</td>
<td>The applicant provided further information in regard to the quality assessment on 24/10/2008 and 11/06/2009.</td>
</tr>
<tr>
<td>5</td>
<td>The application was determined on 02/09/2009.</td>
</tr>
</tbody>
</table>
Steps Taken after Assessment

No non-confidential changes have been made to the market authorisation.
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hypromellose 0.3% w/v Eye Drops Single Dose Unit

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hypromellose 0.32% w/v, expressed as 0.3% w/v.
For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.
Sterile clear solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Acts as a lubricant and artificial tear in the symptomatic treatment of dehydration of the cornea and conjunctiva due to impaired lacrimal secretion and functional disorders as a result of topical or systemic diseases, or caused by deficient or incomplete eyelid closure.

4.2 Posology and method of administration

4.2.1 Dosage
Suitable for use in adults and children.
Unless otherwise directed, instill 1 drop into the conjunctival sac (corner of the eye, nearest the nose) 3 to 5 times per day or as required, to provide sufficient lubrication.
Therapy of dry eye syndrome requires an individual dosage regimen.
Leave an interval of at least 5 minutes before instilling another ophthalmic medication.
4.2.2 Administration
For ocular use only.

4.3 Contraindications

Hypersensitivity to the active substance (hypromellose) or to any of the excipients.

4.4 Special warnings and precautions for use

Stop treatment and consult a physician if irritation persists or worsens or new eye signs or symptoms develop.
Wearers of soft contact lenses should remove their lenses before Hypromellose is administered and should wait for at least 15 minutes before they insert them again.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

Hypromellose can be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Hypromellose on instillation may cause a short term blurring of vision when first used. If affected wait until vision has cleared before driving or operating machinery.

4.8 Undesirable effects

Brief blurred vision or a slight stinging sensation on instilling Hypromellose.
4.9 Overdose

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:
Ophthalmologicals: other ophthalmologicals
ATC code: S01X A20

Hypromellose prolongs adhesion, enhances moistening of the cornea and conjunctiva and allows for a smoother movement of the conjunctiva over the cornea.

5.2 Pharmacokinetic properties

Hypromellose does not permeate the cornea or reach the systemic circulation via the ophthalmic vessels.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate dodecahydrate
Sodium dihydrogen phosphate dihydrate
Sorbitol E420
Water for injections
6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

0.5 ml single dose unit, composed of LDPE. 20, 30, 60 and 120 single dose units.

6.6 Special precautions for disposal

Avoid contamination during use. Hypermellose SDU eye drops are sterile until first opened. For single use only. Each carton contains a patient insert with instructions for use.

7 MARKETING AUTHORISATION HOLDER

Pharma Global Limited
Hudson Road
Sandy Cove
Co Dublin
Republic of Ireland
8 MARKETING AUTHORISATION NUMBER(S)

PL 11185/0006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/09/2009

10 DATE OF REVISION OF THE TEXT

01/10/2009
Labels and Leaflets

PACKAGE LEAFLET: INFORMATION FOR THE USER

HYPROMELLOSE 0.3% w/v eye drops
SINGLE DOSE UNIT
PRESERVATIVE FREE

The name of your medicine is Hypromellose 0.3% w/v Eye Drops Single Dose Unit. It does not contain any preservative. It is called Hypromellose SDU Preservative Free in this leaflet.

Please read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription, as an over the counter item only in a pharmacy. However, you still need to use Hypromellose SDU Preservative Free 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 SDU Preservative Free is and what it is used for
2. Before you use Hypromellose SDU Preservative Free
3. How to use Hypromellose SDU Preservative Free
4. Possible side effects
5. How to store Hypromellose SDU Preservative Free
6. Further information

1. WHAT HYPROMELLOSE SDU PRESERVATIVE FREE IS AND WHAT IT IS USED FOR

Your drops contain hypromellose as the active ingredient, which is a form of cellulose.
Your drops are used as a tear substitute and lubricant when applied to the eye.
The hypromellose in these drops increases the thickness of the solution which has a moisturising effect and helps the solution to stay in contact with the eye for a longer period of time.
These drops work by soothing the eye and giving tear-like lubrication to the eyes and eye lids.
They are used to treat the symptoms of "dry eye", which is a dehydration of the surface of the eye because no natural tears are being produced. Dry eye can also be caused if it is not possible to close your eyelids partly or completely.

2. BEFORE YOU USE HYPROMELLOSE SDU PRESERVATIVE FREE

Do not use these drops
- if you have been told, or know, that you are allergic (hypersensitive) to any of its ingredients
(see section 6).

Take special care with these drops
- if you wear soft contact lenses – take out your lenses before using Hypromellose SDU Preservative Free and then wait for at least 15 minutes after using these drops before putting your lenses back in.

Using other medicines
- You should wait 5 minutes before using any other eye medication.

Pregnancy and breast-feeding
- These drops can be used if you are pregnant or breast-feeding.

Driving and using machines
- All eye drops can cause a short term blurring of vision when first used so you should wait until your eyes are clear before driving or using machines.

3. HOW TO USE HYPROMELLOSE SDU PRESERVATIVE FREE

Always use your drops exactly as your doctor or pharmacist has told you to. You should check with your doctor or pharmacist if you are not sure.
The medicine is to be used only as drops applied into one or both eye(s).

Dosage
The usual dose is to apply one drop in the corner of the eye, nearest the nose, 3 to 5 times each day or as required to give enough lubrication.
Dry eye is a condition that varies from person to person. Use the drops as often as you think necessary.
Directions for use
- Sit down in front of a mirror so that you can see what you are doing
- Wipe your eyes to clear any residual wateriness or discharge
- Holding the unit by the label end, remove a single-dose unit from the pack.
- Twist the cap off the single-dose unit.
- Pull your lower eyelid gently down, and then carefully place one drop inside the lower eyelid, in the corner nearest the nose.
- Release the lower eyelid, and blink a few times to make sure the eye is covered by the liquid.
- Repeat the procedure for your other eye.
- When you have finished, throw away the single-dose unit.

Always read the label before using this medicine.

If you use more Hypromellose SDU Preservative Free than you should
If you accidentally use a larger dose than recommended, this may cause some blurring of vision, which will soon pass.

Make sure you know how and when to use your medicine. If you are not sure about using your drops, ask your pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Hypromellose SDU Preservative Free can cause some side effects, although not everybody gets them. If you experience any difficulty, stop using your drops and talk to your doctor or pharmacist.

Like all eye drops you may briefly have blurred vision or a slight stinging feeling after using your drops. There is also a slight possibility that irritation or itching of the eye may occur in a very small number of people.

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

5. HOW TO STORE HYPERMELLOSE SDU PRESERVATIVE FREE

- Keep out of the reach and sight of children.
- Do not use this medicine after its expiry date.
- Check the expiry date on the label before you begin to use your medicine.
- The expiry date refers to the last day of that month.
- If the expiry date has passed, take the medicine back to your pharmacist.
- Keep the eye drops at normal room temperature (do not store above 25°C).
- Protect from light.
- Your eye drops are sterile until first opened. It is important to keep the drops as clean as possible during use.
- Your drops come in single-dose, single-use units, which should be thrown away immediately after use.
- 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 SDU Preservative Free contains
The active ingredient is Hypromellose 0.3% w/v.
The other ingredients are Sorbitol, Disodium Phosphate Dodecahydrate, Sodium Dihydrogen Phosphate Dihydrate and Water for Injections.

What Hypromellose SDU Preservative Free looks like and contents of the pack
Your eye drops are artificial tears and are supplied in plastic single-dose units in pack sizes of 20, 30, 60 and 120.
Each single dose unit has a volume of 0.5 ml. Your drops contain no preservative, therefore each unit is for single-use only. These eye drops are a clear solution.
Your drops do not contain a preservative and can be used by patients who are hypersensitive to preservatives or who wear contact lenses.

This medicine is for you, never give it to anyone else, even if they appear to have the same symptoms as you.

Return any unused medicine to your pharmacist.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:
The manufacturer is:
Pharma Global Limited
Dr Gerhard Mann Chem-pharm
Hudson Road, Sandy Cove, Co Dublin
Fabrik GmbH
Ireland
13381 Berlin
Pl 11185/0006
Germany

This leaflet was last approved in September 2009.
HYPROMELLOSE PACK 20
0.3% w/v Eye Drops Single Dose Unit
Preservative free.
For ocular use.

Hypromellose is an aqueous artificial tear product for the treatment of dry eyes.

30 x 0.5 ml single dose units
Aqueous tear substitute with increased viscosity for ocular use.

HYPROMELLOSE PACK 30

UKPAR Pharma Global Ltd, Hypromellose 0.3% w/v Eye Drops Single Dose Unit