SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hypromellose Eye Drops BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: 3 mg Hypromellose (0.3% w/v)

Excipient(s) with known effect:
Benzalkonium chloride 0.10 mg/ml
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, Solution.

A clear to slightly opalescent colourless, slightly viscous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Hypromellose is used as artificial tears to prevent damage to the cornea in patients with keratoconjunctivitis sicca accompanying rheumatoid arthritis, xerophthalmias 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 e.g. air-conditioning, central heating, wind and sun).

4.2 Posology and method of administration

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

Method of administration: For ocular use only.

4.3 Contraindications

Hypersensitivity to the active substance, Hypromellose or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

May cause transient mild stinging or temporary blurred vision. If irritation persists or worsens, or headache, eye pain, vision changes or continued redness occur, patients should discontinue use and consult a physician or pharmacist (see section 4.8).

In order to preserve the sterility, the dropper should not be allowed to touch any part of the eye or any other surface. (Label warning: Do not touch any part of the eye with the dropper).

This formulation of Hypromellose eye drops contains 0.1mg/ml benzalkonium chloride as preservative which may be deposited in soft contact lenses. Hence, Hypromellose should not be used while wearing these lenses. The lenses should be removed before instillation of the drops and not reinserted earlier than 15 minutes after use.

Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and
may affect the tear film and corneal surface. Should be used with caution in dry eye patients
and in patients where the cornea may be compromised. Patients should be monitored in case of prolonged use.

4.5. Interactions with other Medicinal Products and other Forms of Interaction

Hypromellose prolongs the contact time of topically applied drugs commonly used in ophthalmology.

4.6. Fertility, pregnancy and lactation

Fertility
Studies have not been performed to evaluate the effect of topical ocular administration of hypromellose on fertility. Hypromellose is a pharmacologically inert compound and it would not be expected to have any effect on fertility.

Pregnancy
There are no or limited amount of data from the use of ophthalmic hypromellose in pregnant women. Systemic exposure to hypromellose following topical ocular administration is negligible and the product has no pharmacological properties.

Lactation
It is unknown whether topical hypromellose/metabolites are excreted in human milk. No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding women to hypromellose is negligible. In addition to this, hypromellose is pharmacologically inert.

4.7 Effects on ability to drive and use machines

May cause transient blurring of vision on instillation. Do not drive or operate hazardous machinery unless vision is clear.

4.8 Undesirable effects

The following adverse reactions have been reported following administration of Hypromellose.

Frequency cannot be estimated from the available data:

Eye disorder:

- transient mild stinging or vision blurred,
- eye pain,
- foreign body sensation in eyes,
- eye irritation,
- ocular hyperaemia.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow card scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Due to the characteristics of this preparation, no toxic effects are to be expected with an ocular overdose of this product, nor in the event of accidental ingestion of the contents of one bottle.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Ophthalmologicals: other ophthalmologicals

ATC code: SO1X A20

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.

5.2. Pharmacokinetic properties

Not applicable to topical (ophthalmic) preparations.

Hypromellose is an inert substance. It has no pharmacological activity and not absorbed systemically. Hence, the pharmacokinetic properties have not been studied.

5.3. Preclinical safety data

Hypromellose is an inert substance and is not expected to be absorbed systemically. Hence, although no systemic toxicity studies have been conducted it is not expected to demonstrate any systemic toxicity or to have any effect on reproductive processes.

Similarly no specific local ocular toxicity or irritation studies have been conducted; however no adverse effects are anticipated. Indeed, hypromellose ophthalmic solution is used as a control in some ophthalmic drugs studies because of the acknowledged low level of toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Potassium chloride
Borax
Boric acid
Benzalkonium chloride solution
Water for injections
Sodium hydroxide solution (for pH adjustment)
Hydrochloric acid (for pH adjustment)

6.2. Incompatibilities

Not known

6.3 Shelf life

Unopened: 24 months
After first opening: Discard the bottle 28 days after opening, even if there is solution remaining.

6.4 Special precautions for storage

Protect from light.
Do not store above 25°C

6.5 Nature and contents of container

Pack Type A

Low density polyethylene bottle with a polystyrene spiked cap.
Pack size: 10 ml
Pack Type B

Low density polyethylene (LDPE) vial with an insert cap assembly, comprising of white coloured HDPE screw cap over a LDPE nozzle with tamper-evident LDPE dust cover sealing the vial cap.
Pack size: 10 ml

6.6 Special precautions for disposal and other handling

Do not touch the dropper tip to any surface as this may contaminate the contents.

If the drop of medication is not retained in the eye upon dosing for any reason, instill another drop.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 15872/0005

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16th January 1998 / 01st July 2008

10 DATE OF REVISION OF THE TEXT

12/08/2020