SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Moistur-eyes 'dry eye' drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Hypromellose eye drops contain 0.3% solution of hypromellose, buffered to pH 8.4

Excipients with known effect

Benzalkonium chloride solution

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Topical ophthalmic (drops)

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.

4.2 Posology and method of administration

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

4.3 Contraindications

Hypersensitivity to the active substance 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).

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

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

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 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 disorders:

- transient mild stinging or temporarily blurred vision,
- 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 the 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

None stated

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals - other ophthalmologicals

ATC code: S01XA20

Hypromellose is a soothing emollient solution with properties and uses similar to those of methylcellulose. Its advantages over methycellulose 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, hypromellose is not systemically absorbed.

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
Purified water

6.2 Incompatibilities

None stated

6.3 Shelf life

Unopened: 24 months
After first opening: 28 days

6.4 Special precautions for storage

Store below 25°C, protect from light

6.5 Nature and contents of container

A polypropylene dropper bottle fitted with a low density polyethylene nozzle and a high density polyethylene tamper evident cap

6.6 Special precautions for disposal

1. Wash your hands
2. Tilt the head backwards and line up the eye dropper bottle over the eye
3. Squeeze the bottle gently to release a couple of drops into the eye
4. Blinking will insure the film of drops is distributed over the whole eye.
5. Repeat three times daily as needed

Warnings: This product contains benzalkonium chloride as a preservative and should not be used with soft contact lenses.
Do not allow the bottle to touch the eye as this can cause infection.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

PL 13606/0003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/10/95 / 25/10/00

10. DATE OF REVISION OF THE TEXT

30/01/2018