

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

For excipients, see 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 is one or two drops topically instilled into the eyes three times daily as needed, or as directed by a physician.

Hypromellose drops are suitable for use by both adults and children over 3 years of age.

4.3 Contraindications

Hypersensitivity to any component of the product.

The product contains boric acid which is contraindicated in infants or young children up to 3 years of age.

4.4 Special warnings and precautions for use

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

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).

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

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

There is insufficient evidence as to 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 blurring of vision on instillation. Do not drive or operate hazardous machinery unless vision is clear.

4.8 Undesirable effects

May cause transient mild stinging or temporarily blurred vision.

Eye disorders: 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

None stated

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hypromellose is a soothing emollient solution with properties and uses similar to those of methylcellulose but has advantages since 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

None stated

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

24 months

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.

Discard the eye drops 28 days after opening.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

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9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/10/95 / 25/10/00

10. DATE OF REVISION OF THE TEXT

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