

# Hyprosol Eye Drops

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## **1. Name of the medicinal product**

HYPROSOL Eye Drops

## **2. Qualitative and quantitative composition**

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

Excipient(s) with known effect:

Benzalkonium chloride

For the full list of excipients, see section 6.1.

## **3. Pharmaceutical form**

Eye drops, Solution.

A clear 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 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 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](http://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: S01X 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**

Disodium Hydrogen Phosphate Dihydrate BP

Sodium Hydrogen Phosphate Dihydrate BP

Sodium Chloride USP, Ph. Eur.

Benzalkonium Chloride Solution BP

Water for injections BP

#### **6.2 Incompatibilities**

Not known

#### **6.3 Shelf life**

Unopened: 36 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**

10 ml white LDPE dropper bottle with HDPE tamper evident screw cap (Gamma sterilized) and white LDPE dropper (Gamma sterilized)

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**

BEXIMCO PHARMACEUTICALS LTD.

19 Dhanmondi R/A, Road No. 7

Dhaka-1205, Bangladesh

**8. Marketing authorisation number(s)**

186-618-052

**9. Date of first authorisation/renewal of the authorisation**

04.10.2009

**10. Legal Category**

POM