SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

AQUA TEARS EYE DROPS 10ml (Hydroxypropyl Methylcellulose Eye Drops)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition

Hydroxypropyl Methylcellulose USP ….0.7%w/v
Borax BP…….0.19%w/v
Boric Acid ……...0.2%w/v
Sodium Chloride BP ……...0.45%w/v
Potassium Chloride BP ……...0.37%w/v
Benzalkonium Chloride NF…….0.01%w/v
(As preservative)
Sterile Aqueous Base.…….……...…..Q.S.

3. PHARMACEUTICAL FORM

Dosage Form: Ophthalmic Solution (Eye Drops)
Description of Product: Clear colorless solution filled in 10ml plastic vials.

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 eg 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.
Administration: For ocular use only.

4.3 Contraindications

Hypersensitivity to active substance, Hypromellose or to any of the excipients

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.

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

Remove contact lenses prior to application and wait at least 15 minutes before reinserting. Benzalkonium chloride is known to discolour soft contact lenses.

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

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

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

Boric Acid, Borax, Benalkonium Chloride Solution, Sodium Chloride, Potassium Chloride

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

After the first opening of the container, the sterile ophthalmic suspension should not be used longer than four weeks.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container and special equipment for use, administration or implantation

Clear colorless solution filled in 10ml plastic vials.

Secondary packaging

Each vial is packed in a unit carton.

6.6 Special precautions for disposal and other handling

No special requirements

7. APPLICANT/MANUFACTURER

NITIN LIFESCIENCES LIMITED

Rampur Road, Paonta Sahib
Dist. Sirmour-173025,
Himachal Pardesh, India.