

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

# Sodium Hyaluronate Eye Drops

## OCUSOOTHE<sup>®</sup>-DUO

ओक्यूसुथ - डुओ

### COMPOSITION:

Sodium Hyaluronate BP.....0.1 % w/v

Stabilized Oxychloro Complex..... 0.01%w/v

(As preservative)

Sterile Aqueous Buffered Vehicle q.s.

With Sodium Carboxymethylcellulose IP, Glycerin IP, Boric Acid IP, Calcium Chloride IP, Erythritol USNF, Levocarnitine USP, Potassium Chloride IP, Borax BP & Sodium Citrate IP.

### PHARMACEUTICAL FORM

Eye Drops

### THERAPEUTIC INDICATION

For temporary relief from burning, irritation and discomfort due to dryness of the eye, and relief from discomfort due to environmental elements such as wind, smoke, sun, dry air, air conditioning & prolonged use of computers.

### APPLICATION AND ADMINISTRATION

Instill 1 or 2 drops in the affected eye(s) as needed or as directed by the physician.

### CONTRAINDICATIONS

Known hypersensitivity to active component or any ingredient used in this product.

### SPECIAL WARNINGS AND PRECAUTIONS

Do not allow the tip to make contact with the eyes. Do not instill over contact lenses.

### DRUG INTERACTIONS

There are no known drug interactions. In cases of co-administration with other eye medication, should always be applied last, after an interval of at least 5 minutes.

### PREGNANCY AND LACTATION

Reproductive studies have not demonstrated any risk, but no controlled studies in pregnant women are available. Sodium Hyaluronate has a purely physical effect on the eyes without being absorbed and hence can be used during pregnancy and lactation.

### EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Patients who experience blurred vision after application of the eye drops should not drive or use machinery until their vision has cleared.

## UNDESIRABLE EFFECTS

Ocusoothe Duo eye drops rarely causes serious side effects or an allergic reaction. For a few moments, vision may be temporarily blurred after instillation of the eye drops. Minor irritation, burning may temporarily occur.

## OVERDOSE

There are no known reports of overdosing.

## PHARMACODYNAMICS

Sodium Hyaluronic acid contains a highly purified specific fraction of Sodium salt of Hyaluronic acid produced by bacterial fermentation and is therefore free from animal proteins. Hyaluronic acid is a natural polymer, which is present throughout the human body and also in the structures of human eyes. Its main physical characteristic is viscoelasticity. This means that Sodium Hyaluronic acid has a high viscosity between blinks and a low viscosity during blinking, ensuring efficient coating of the surface of the eye. Hyaluronic acid also possesses mucoadhesive properties and the ability to entrap water, thus resembling tear mucus glycoprotein. This, together with the coating properties of Hyaluronic acid results in an increased pre-corneal residence time and tear film break-up time and therefore a longer lubrication of the corneal surface. The protective coating of the eye surface offered by Sodium Hyaluronic acid helps prevent dryness and irritation.

## PHARMACOKINETICS

Due to its high molecular weight, Sodium Hyaluronate is not expected to pass through the conjunctiva and the corneal epithelium. Following intraocular administration of Sodium Hyaluronate, the half-life ( $t_{1/2}$ ) for elimination from the aqueous humour was around 10.5 hrs after administration.

## STORAGE

**Store below 30°C. Protect from light & moisture. Do not freeze.**

Keep out of reach of children.

**NOT FOR INJECTION. FOR EXTERNAL USE ONLY.**

Use the solution within one month after opening the container.

**PRESENTATION:** Ocusoothe-Duo Eye Drops are available in 5 ml and 10 ml packs.

Manufactured by:

Akums Drugs & Pharmaceuticals Ltd.

2,3,4 & 5, Sector-6B, I.I.E., SIDCUL,

Haridwar-249 403.

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