EyeKare

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

HALOEYE S™

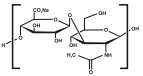
# SODIUM HYALURONATE OPHTHALMIC SOLUTION 0.1% W/V

**COMPOSITION**

Sodium Hyaluronate BP 0.1% w/v, Stabilized Oxychloro Complex (as Preservative) 0.005% w/v, Sterile Aqueous Buffered Vehicle q.s.

**Other Ingredients :** L-Proline USP, L-Lysine Hydrochloride USP, L-Leucine USP, Glycine IP

Molecular formula: $(C_{14}H_{20}NNaO_{11})_n$



Structural formula of sodium hyaluronate

Hyaluronic acid, a glycosaminoglycans, is a highly viscous and elastic biopolymer occurring in many connective tissues throughout the body, including both the aqueous and the vitreous humor. Hyaluronic acid is a high molecular weight unbranched polysaccharide formed by a linear chain.
It comprises repeating dissacharide units of glucuronic acid and N-acetyl-D-glucosamine.
All strengths mentioned in this document might not be available in the market.

**PHARMACEUTICAL FORM :** Ophthalmic solution.

**CLINICAL PARTICULARS**

**Therapeutic Indications:**

0.1% sodium hyaluronate, ophthalmic solution are used for treatment of dry eyes and burning sensations due to environmental conditions.

**Dosage and Method of Administration :**

**Posology**

Normally one drop of HALOEYE S is applied three times a day into each eye. If necessary it can also be used more frequently and as often as required. However a more frequent application (i.e. more than 10 times per day) of HALOEYE S should be done under an ophthalmologists' control.

HALOEYE S can be used while wearing contact lenses. Wearing soft or hard contact lenses can be more comfortable by using HALOEYE S as it does not form crusts or residues.

HALOEYE S is suitable for long-term treatment.

**Method of administration**

For ocular use

**Use in Elderly :** Dosage recommendations and indications for use in elderly have not been established.

**Use in Patients with Renal Impairment :** Not applicable

**Use in Patients with Hepatic Impairment :** Not applicable

**Use in Children :** Dosage recommendations and indications for use in children have not been established.

**Contraindications :**

Hypersensitivity to any of the ingredients. In the event of persisting eye irritation discontinue use and consult your doctor.

**Special Warnings and Special Precautions for Use :**

Do not touch the nozzle and do not allow the nozzle tip to touch the eye during use.
HALOEYE S should not be used at the same time as other ophthalmic drugs. If any other eye drops have to be used there should be an adequate gap before applying HALOEYE S. Eye ointments should, however always be administered after die application of HALOEYE S.

**Interaction with Other Medicinal Products and Other Forms of Interaction :**

As HALOEYE S reaches its target directly by topical application and has primarily a physical effect (wetting of the surface) and no systemic effect, no drug interactions other than the physical interaction of topically applied eye drops are known.

**Pregnancy and Lactation :**

HALOEYE S can be applied during pregnancy and lactation as there is no pharmacological effect.

**Effects on Ability to Drive and Use Machines :**

HALOEYE S ophthalmic solution may cause blurred vision for a short time after application even at normal dosages and with proper use. This can subsequently impair reaction time while driving or operating machinery.

**Undesirable Effects :**

HALOEYE S is well tolerated even when used over a period of time. Safety data does not provide any evidence that would represent an unacceptable hazard to its use in humans. In rare cases hypersensitive reactions like burning, itching, tearing has been reported which recedes immediately on discontinuation of HALOEYE S.

**Overdose :**

Overdosage is unlikely to occur with this topical preparation.

**PHARMACOLOGICAL PROPERTIES :**

**Pharmacodynamic Properties**

Dry eye patients present with instability of the precorneal tear film which breaks up much earlier than normal. The instability of the precorneal tear film leads to dry eye symptoms such as the sensation of sand in the eye, recurrent blurred vision, itching, smartness, and the sensation of dryness.

The main objective of dry eye treatment is to increase the precorneal tear film stability Hyaluronic Acid (HA) as a tear substitute behaves like a pseudoplastic fluid. This means that at very low shear the solution has a very high viscosity and relatively low elasticity, and at higher shear the solution is extremely elastic. These viscoelastic properties are important to lubricate. In addition, the water binding capacity of HA keeps the eye's surface wet. HA solution forms a lubricating moisture film on the surface of the eye that is not easily rinsed off. The macromolecule sodium hyaluronate has bioadhesive and mucomimetic properties when applied to the eye because of interactions with the precorneal mucin layer. By this, the solution spreads out very well and forms a regular, stable and long-lasting tear film. It however does not cause blurred vision and it protects the eyes from dryness and irritation for a long time.

In HALOEYE S, Sodium Hyaluronate acts in a physico-chemical manner without pharmacological action by lubricating the ocular surface HA binds to many extracellular matrix molecules, specifically to cell bodies through cell surface receptors like CD44. Expression of CD44 is increased in patients with moderate dry eye and superficial keratitis. HA might have a direct role in control of ocular surface inflammation in dry eye patients because it is associated with a decreased expression of CD44 in patients with moderate eye and superficial keratitis.

The duration of contact with the ocular surface (the so-called residence time) is important for the efficacy of artificial tears. Wearing soft or hard contact lenses can be more comfortable by using HALOEYE S as it does not form crust or residue.

It is a phosphate-free, citrate buffered formulation. This can improve the safety as the formulation of insoluble calcium phosphate deposits in the cornea is not formed after instillation of these eye drops.

**Pharmacokinetic Properties :**

0.1% sodium hyaluronate, ophthalmic solution reach their target directly by topical application and have primarily a physical effect (wetting of the surface). The substance does not become systemically available and are not metabolised in the human body. It is washed out of the eye after a while.

**Preclinical Safety Data :**

There is no data known about any toxic effect of sodium hyaluronate.

Because sodium hyaluronate is a naturally physiologic substance occurring in the eye but also in other parts of the body, the substance is very well tolerated in general.

**Incompatibilities :** None known

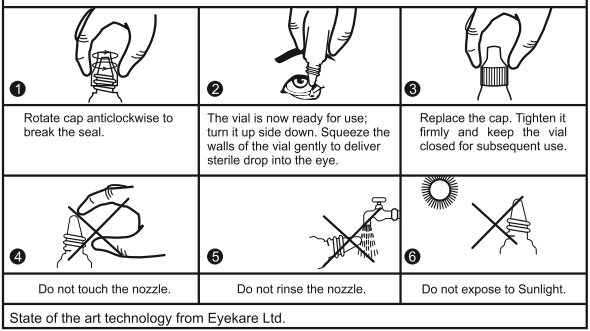
**PACKING :** HALOEYE S ophthalmic solution are available in 5ml & 10 ml in ***Iyondellbasel Purell*** low density polyethylene dispensing system consisting of plastic bottle with good flexibility. Tamper evidence ring around the closure and neck area of the bottle.

**STORAGE INSTRUCTIONS : Store at a temperature not exceeding 30°C and protect from light.** Use the solution within one month after opening the container.

For external use only.

KEEP OUT OF REACH OF CHILDREN.

**INSTRUCTIONS FOR USE**






Marketed by:

EyeKare

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