Wearing soft or hard contact lenses can be more comfortable by using **OPSION™ HA** as it does not form crusts or residue.

Deposits in the cornea is not formed after instillation of these eye drops.

4.2 Pharmacokinetic Properties: 0.1% sodium hyaluronate eye drops 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.

4.3 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

5. PHARMACEUTICAL PARTICULARS
5.1 Incompatibilities: None known

5.2 Shelf Life: Refer to Pack. Refer the outer carton for the date of expiry. The date of expiry is the last day of the month.

Use the solution within one month after opening the container

5.3 Special Precautions for Storage: Store in a cool place. Protect from light.

5.4 Nature and Contents of Container: OPSION™ HA Eye Drops are supplied in 10 mL (Physician's sample), 5mL and 10 mL (Sales Pack) plastic container.

5.5 Instructions for Use and Handling: WARNING: (i) if irritation persists or increases, discontinue the use and consult physician.
(ii) Do not touch the nozzle tip or any other dispensing tip to any surface since this may contaminate solution.

Marketed by :
ALLERGAN INDIA PRIVATE LIMITED

Manufactured in India by :
Piramal Enterprises Limited
Plot No. 67-70, Sector- II, Pithampur-454 775, Dist. Dhar,
Madhya Pradesh

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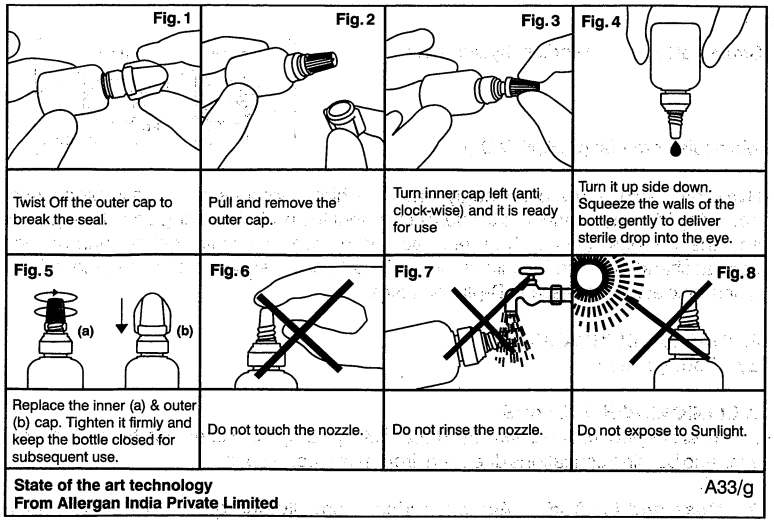


For the use only of Registered Medical Practitioners or a Hospital or a Laboratory

SODIUM HYALURONATE 0.1% EYE DROP

OPSION™ HA

Eye Drop

Allergan™

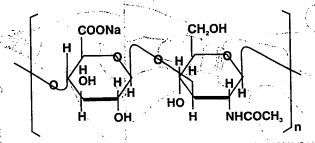
1. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each ml contains;

Sodium Hyaluronate Ph. Eur	1 mg
Stabilized Oxy-Chloro Complex (Purite)	0.1 mg
Purified Water I P	q.s.

Excipients: Erythritol, Boric acid, Glycerin, Sodium carboxymethyl cellulose, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Potassium chloride, Sodium borate, Sodium citrate dihydrate, Sodium hydroxide pellets.

Sodium hyaluronate is a white or almost white, very hygroscopic powder or a fibrous aggregate, sparingly soluble to soluble in water, practically insoluble in acetone and in ethanol.

Structural formula of sodium hyaluronate



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

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 repealing disaccharide units of glucuronic acid and N-acetyl-D-glucosamine.

2. PHARMACEUTICAL FORM

Eye drops solution

3. CLINICAL PARTICULARS

3.1 Therapeutic Indications: **OPSION™ HA** eye drops are used for treatment of dry eyes and burning sensations due to environmental conditions

3.2 Dose and Method of Administration: Normally one drop of **OPSION™ HA** 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 **OPSION™ HA** should be done under the supervision of an Opthalmologist. **OPSION™ HA** can be used while wearing contact lenses. Wearing soft or hard contact lenses can be more comfortable by using **OPSION™ HA** as it does not form crusts or residues. **OPSION™ HA** is suitable for long-term treatment

Method of administration: For ocular use

Use in the 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

Pregnancy and Lactation: **OPSION™ HA** can be applied during pregnancy and lactation as there is no pharmacological effect

Effects on Ability to Drive and Use Machines: **OPSION™ HA** eye drops 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

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

3.4 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.

OPSION™ HA 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 **OPSION™ HA**. Eye ointments should, however always be administered after the application of **OPSION™ HA**

3.5 Interaction with Other Medicinal Products and Other Forms of Interaction: As **OPSION™ HA** 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

3.6 Undesirable Effects: OPSION™ HA is generally well tolerated even when used over a long 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

3.7 Overdose: Overdosage is unlikely to occur with this topical preparation

4. PHARMACOLOGICAL PROPERTIES

4.1 Pharmacodynamic Properties: Dry eye patients present with instability of the pre-corneal tear film which breaks up much earlier than normal. The instability of the pre-corneal tear film leads to dry eye symptoms such as the sensation of sand in the eye, recurrent blurred vision, itching and the sensation of dryness

The main objective of dry eye treatment is to increase the pre-corneal 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 pre-corneal 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 **OPSION™ HA**, 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.