



Sodium Hyaluronate Eye Drops

Clearvue®

Eye Drops

क्लियरव्यू

3035503

COMPOSITION

Sodium Hyaluronate BP	0.3% w/v
Stabilized Oxychloro Complex (As preservative)	0.01% w/v
Sterile Aqueous Vehicles	q.s.

Other Ingredients:

Trehalose USP, Taurine USP, Levocarnitine IP, Glycerin IP.

DOSAGE FORM AND STRENGTH

Ophthalmic solution; Sodium Hyaluronate 0.3% w/v Eye Drops

CLINICAL PARTICULARS

Therapeutic indication

As directed by the Physician.

Posology and method of administration

Posology

As directed by the Physician or Ophthalmologist.

The dosage may be adjusted according to the patient's symptoms.

Method of administration: For ophthalmic use only.

At the time of administration:

- (1) Instruct the patient to be careful not to touch the tip of the bottle to the eye directly in order to avoid the contamination of the drug.
- (2) Instruct the patient, if any other ophthalmic drug is used, to wait at least five minutes between applying this product and any other ophthalmic drug.
- (3) Instruct the patient not to use this product while wearing soft contact lenses.

Contraindications

This eye drop is contraindicated in patients with known hypersensitivity to active component or to any of the ingredient used in this product.

Special warnings and precautions for use

Instruct the patient to be careful not to touch the tip of the bottle to the eye directly in order to avoid the contamination of the drug.

Hypersensitivity such as blepharitis and eyelid dermatitis, and ophthalmic adverse reactions such as itching, irritation, conjunctivitis, conjunctival injection, corneal disorders including keratitis superficialis diffusa (incidence 0.1% to <5%) may occur. Eye discharge (incidence <0.1%) may be produced.

Sodium hyaluronate eye drop should not be administered while using contact lenses. Instruct the patient, if any other ophthalmic drug is used, to wait at least five minutes between applying this product and any other ophthalmic drug. This eye drop is meant for external use only. Not for injection.

Drugs interactions

There are no known drug interactions.

Do not use sodium hyaluronate eye drop at the same time as any other drug or product applied to the eye as it may modify their effects. In cases of co-administration with other eye medication, should always be applied last, after an interval of at least 5 minutes.

Use in Specific populations

1. Pregnancy

Adequate and well-controlled studies in humans have not been done. No evidence of harm to the fetus was seen in rats and rabbits given hyaluronate sodium in doses of up to 1.43 mg/kg, approximately 11 times the MRHD, per treatment cycle.

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.

2. Lactation

It is not known whether hyaluronate sodium is distributed into breast milk. However, problems in humans have not been documented.

3. Fertility

No evidence of impairment of fertility was seen in rats and rabbits given hyaluronate sodium in doses of up to 1.43 mg per kg of body weight (mg/kg), approximately 11 times the maximum recommended human dose (MRHD), per treatment cycle.

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

Sodium hyaluronate 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 reduces immediately on discontinuation. Sodium hyaluronate 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. If the following adverse reactions are observed, appropriate measures such as discontinuing administration should be taken.

Ophthalmic (5% > \geq 0.1%): Itching, irritation, conjunctivitis, conjunctival injection, corneal lesion such as keratitis superficialis diffusa, and Eye discharge (<0.1%).

Hypersensitivity (5% > \geq 0.1%): Blepharitis, eyelid dermatitis.

Overdose

Overdosage is unlikely to occur with sodium hyaluronate preparations. There are no known reports of overdosing.

PHARMACOLOGICAL PROPERTIES

Mechanism of Action

Sodium hyaluronate binds to fibronectin and accelerates the adhesion and extension of epithelial cells. Sodium hyaluronate also has an excellent water-holding property because each sodium hyaluronate molecule can retain many water molecules.

Pharmacodynamic properties

Sodium hyaluronate 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 hyaluronate 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 hyaluronate acid helps prevent dryness and irritation.

Pharmacokinetic properties

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

NONCLINICAL PROPERTIES

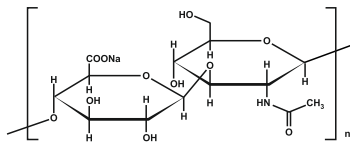
Animal Toxicology or Pharmacology

Results of acute, sub-acute and chronic toxicity studies together with the results of the foetal toxicity, fertility, peri- and post-natal toxicity studies show that hyaluronic acid is very well tolerated. In addition, animal studies show that repeated topical ocular administration of hyaluronic acid is also well tolerated. Toxicity: >2400 mg/kg (mouse, oral, sodium salt) >4000 mg/kg (mouse, subcutaneous, sodium salt) 1500 mg/kg (mouse, intra-peritoneal, sodium salt).

DESCRIPTION

This formulation contains the active ingredient sodium hyaluronate (hyaluronic acid), a natural component of tear film, which has high water retention ability; increases tear film stability and accelerate corneal wound healing. One drop in each eye 3-4 times daily improves the symptoms of dry eye. Sodium Hyaluronate eye drops are also known as artificial tear. Each ml contains sodium hyaluronate 3 mg.

The following is the chemical structure of sodium hyaluronate.



Sodium Hyaluronate

PATIENT COUNSELLING INFORMATION

Sodium hyaluronate eye drops moisten, soothe and lubricate the surface of your eye, making it feel more comfortable. These eye drops help you provide soothing relief from the symptoms of dry eyes, such as soreness, irritation or a gritty sensation. This happens when your eyes does not produce enough tears to keep them moist, prolonged use of computer screens (where you tend to blink less and thus not lubricate the eyes sufficiently), or drying atmospheric conditions such as air-conditioning, central heating or pollution. Sodium hyaluronate has also been shown to stimulate the development of epithelial cells on the eye's surface, which can help to heal damage to the surface of the eye resulting from lack of lubrication. You can use the drops as often as required or as advised by the Physician or Ophthalmologist.

General information

- Use one drop into the eye (or eyes) affected by dryness. Many people find it is sufficient to use the drops three or four times a day, but you can use the drops as often as you need to if your eyes are very dry. If the drops have been prescribed for you, then follow the directions given by your doctor.
- Please take care that the dropper doesn't touch your eye, your fingers, or any other surface. This could contaminate the drops left in the bottle.
- If you forget to use the drops at your 'usual' time, do not worry, just put them in when you remember. Do not 'double up' the number of drops you use to make up for forgetting to use them.
- When first put in, eye drops may cause blurred vision. This should quickly clear. Make sure you can see clearly again before you drive, or before you use tools or machines.
- If you are using any other eye drops or ointments leave about ten minutes between applying each one. It is usually recommended that you use the sodium hyaluronate drops last. This is so that the drops stay in contact with your eye

and lubricate it for as long as possible.

- Do not wear soft contact lenses while you are using the drops unless your doctor or pharmacist has advised you otherwise. This is because there is a preservative in bottles of eye drops which can affect soft contact lenses. There is no preservative in the single-use units.
- If your symptoms do not improve within a few days, see your doctor for advice.
- Keep all medicines out of the reach and sight of children.
- Store in a cool, dry place, away from direct heat and light.
- Always check the expiry date on the label, and for how long you can use the drops once the container has been opened. Many eye drops only keep for four weeks once the container has been opened, in order to reduce the risk of eye infections.

Before using sodium hyaluronate

To make sure this is the right treatment for you, before you start using the eye drops it is important that your doctor or pharmacist knows:

- If you wear soft contact lenses.
- If you have ever had an allergic reaction to a preservative in eye drops.

How to use sodium hyaluronate eye drops

- Wash your hands well before you use the drops.
- Remove the cap from the bottle.
- Tilt your head back a little and pull the lower lid of your eye downwards to form a pocket hold the bottle (or single-use unit) upside down near to your eye. Try not to touch your eye as you do this. Apply enough pressure to release one drop into your eye. Only use a second drop if the first drop missed going into your eye.
- Close your eye for a minute or two, and press gently on the side of your nose where the corner of your eye meets your nose. This helps to stop the drop from draining away and keeps it in your eye.
- Repeat the process in your other eye if you have been told to use the drops in both eyes.
- Replace the cap (or if you are using a single-use dose unit, throw the used unit away).

PHARMACEUTICAL PARTICULARS

Incompatibilities

Not known.

Shelf-life

See on pack

Packaging information

Clearvue Eye drops is available in 10 ml container. Use the solution within one month after opening the container.

Storage and handling instructions

Store below 25°C. Protect from light & moisture. Do not freeze.

KEEP OUT OF THE REACH OF CHILDREN.

FOR EXTERNAL USE ONLY.

NOT FOR INJECTION.

FOR OPHTHALMIC USE ONLY.

Manufactured by :
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