SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

LUROAN 0.15% Eye Drops, Solution
Sterile

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 mL solution contains;
Active substance:
Sodium hyaluronate…….1.5 mg

Excipients:
Benzalkonium chloride……..0.05 mg
Disodium hydrogen phosphate dodecahydrate…..0.56 mg
Sodium dihydrogen phosphate (anhydrous)……..0.04 mg
For the list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution.
Clear, colorless, particle-free solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

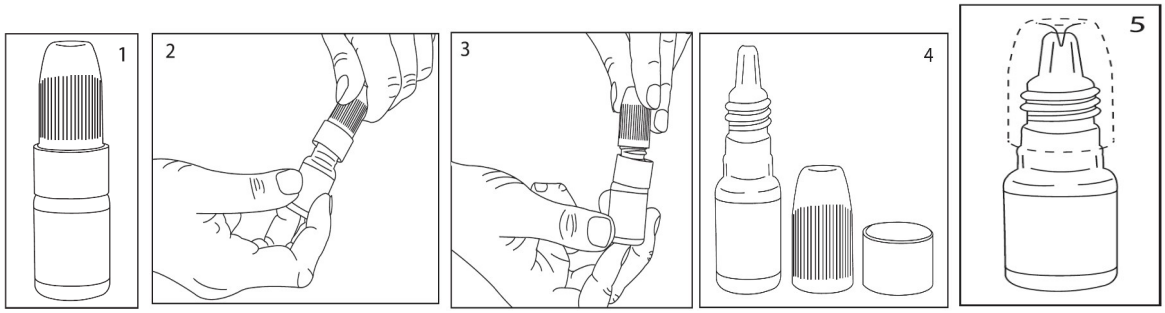
It is used in the symptomatic treatment of dry eye syndrome.

4.2 Posology and method of administration

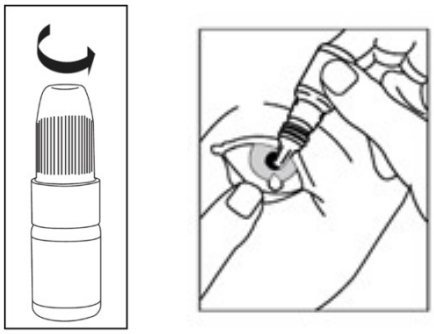
Posology:
Unless otherwise recommended by the physician, it is recommended to instill 1 drop into the eye up to 6 times a day.
The medicine should not be used in treatments lasting more than one month.

Frequency and duration of administration:
The duration of treatment with LUROAN should be determined by the physician depending on the response to treatment.

Method of administration:
- For ophthalmic use only.
- Applied to the eyes.
- To pierce the plastic bottle, the cap should be turned towards the pointed end. The bottle should be closed by turning the pointed end.
- When applying the medicine, the tip of the container should not be touched by the tip of the packaging or any other surface, including the eyes or hands.
- Before use, make sure that the packaging is not damaged.
- The bottle should be used within 28 days after opening.



1. Open the cap of the bottle.
2. Remove the ring under the cap (see Figure 3 and Figure 4).
3. Close the cap again without the ring. The plastic pin inside the cap will pierce the tip of the bottle (see Figure 5).
4. Wash your hands and sit in a comfortable position.



5. Using your finger, gently pull down the lower eyelid of the affected eye.
6. Place the tip of the dropper close to the eye, but do not touch it.
7. Slowly squeeze the dropper and place ONLY one drop in the eye. Then release the lower eyelid.
8. Press the corner of the eye on the nose side with your finger. It should be kept like this for about a minute with the eyes closed.
9. If your doctor has told you to use the medication in both eyes, repeat the same procedure for the other eye.
10. Close the bottle.

Additional information on special populations:

Kidney/Liver failure:

No special dose adjustment is required for patients with kidney/liver failure.

Pediatric population:

In the pediatric age group, LUROAN should be used only if clearly needed and under strict medical control.

Geriatric population:

No special dose adjustment is required in the elderly.

4.3 Contraindications

LUROAN should not be used in the patients with hypersensitivity to any of its ingredients. It is

contraindicated for use with soft contact lenses due to the benzalkonium chloride content.

4.4 Special warnings and precautions for use
Concomitant use with other eye solutions that have detergent or disinfectant effects should be avoided.

This medicine contains 0.05 mg benzalkonium chloride per 1 mL. Benzalkonium chloride can be absorbed by soft contact lenses and may change the color of contact lenses. Contact lenses should be removed before using this medicine and inserted after 15 minutes.

Benzalkonium chloride may cause eye irritation, especially if there is a dry eye condition and corneal (clear layer at the front of the eye) disease. An abnormal sensation, stinging or pain may be felt in the eye after use.

This medicine contains 0.18 mg of phosphate per 1 mL.

If there is severe damage to the transparent layer at the front of the eye (cornea), phosphates can in rare cases cause blurred segments due to calcium deposits during treatment.

4.5 Interaction with other medicinal products and other forms of interaction
Sodium hyaluronate may precipitate in the presence of quaternary ammonium salts. Avoid use with solutions containing these compounds.

Additional information regarding special populations
No interaction studies have been conducted.

Pediatric population
No interaction studies have been conducted.

4.6 Pregnancy and lactation
General recommendation
Pregnancy category: C

Women of childbearing potential/Birth control (Contraception)
There is not adequate data regarding its use in women of childbearing potential.

Pregnancy
There are no adequate studies on the use of LUROAN during pregnancy.
There is no clinical data on the safety of LUROAN during pregnancy.
Animal studies are insufficient regarding effects on pregnancy/and-or/embryonal/fetal development/and-or/birth/and-or/postnatal development (see section 5.3). The potential risk for humans is unknown. LUROAN should not be used during pregnancy unless necessary.

Lactation
Its effect on lactation is unknown.

Reproductive ability/Fertility
There is no known effect on reproductive ability.

4.7 Effects on the ability to drive and use machines
Not applicable.

4.8 Undesirable effects
Undesirable effects reported with sodium hyaluronate treatment in the data from clinical studies are listed in order of frequency as follows:

Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from available data).

Eye disorders
Common:
During treatment, allergic reactions such as eyelid or conjunctival inflammation, itching, burning, redness, increased lacrimation, or superficial keratitis may occur. These reactions are generally temporary and undesirable.

Very rare cases of corneal calcification have been reported in some patients with severely damaged corneas, associated with the use of phosphate-containing eye drops.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4.9 Overdose and treatment
No cases of overdose have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group : Ophthalmologicals, other ophthalmologicals
ATC Code : S01XA20

Mechanism of action:
The sodium hyaluronate contained in LUROAN is a pure and natural polysaccharide characterized by high molecular weight and it is obtained by bacterial fermentation. Pseudoplasticity, high viscosity and high water-binding capacity of polymer lead to stabilization of the lacrimal film and moistening of the ocular surface.

5.2 Pharmacokinetic properties
General properties
Absorption:
No intraocular absorption occurs after application to the conjunctival sac.

Distribution:
Once the polymer is injected into the anterior chamber, it is rapidly eliminated via the aqueous humor flow system. The half-life of 0.2 mL labeled sodium hyaluronate injected into the

anterior chamber of rabbits was found to be 10.5 hours. When the plateau is reached after 24 hours, sodium hyaluronate and its metabolites will be detectable in the blood. When administered intravenously, sodium hyaluronate is rapidly eliminated from the blood, with a half-life of approximately 5 minutes.

Biotransformation:
Most of sodium hyaluronate is metabolized in the liver. Here, this polysaccharide is metabolized into subunits, which will involve in other metabolic processes.

Elimination:
Sodium hyaluronate is largely eliminated (70%) as CO_2 during respiration, while a small portion (22%) is excreted in the urine.

5.3 Preclinical safety data
Studies performed to check ocular tolerability and to demonstrate systemic toxic effects have shown that after repeated application of sodium hyaluronate-based eye drops for 28 days, no significant symptoms of ocular irritation or histological changes developed in the eyes of treated animals.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Benzalkonium chloride
Disodium hydrogen phosphate dodecahydrate
Sodium dihydrogen phosphate (anhydrous)
Sodium chloride
Sodium hydroxide
Hydrochloric acid
Water for injection

6.2 Incompatibilities
Sodium hyaluronate may precipitate in the presence of quaternary ammonium salts. Avoid using it with solutions containing these compounds.

6.3 Shelf life
24 months
After first opening the bottle: Should be used within 28 days.

6.4 Special precautions for storage
Store at room temperature below 25°C.
After first opening the bottle, the medicine should be used within 28 days. During this period, the medicine can be stored at room temperature below 25˚C.

6.5 Nature and contents of the container
The primary packaging material is a transparent, 10 mL low density polyethylene (LDPE) bottle and a twist-off polypropylene white cap. The bottles are presented in cardboard boxes with package leaflet.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local

requirements.

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORIZATION NUMBER

2018/565

9. DATE OF FIRST AUTHORIZATION / RENEWAL OF AUTHORIZATION

Date of first authorization : 10.10.2018
Date of renewal :

10. DATE OF REVISION OF THE TEXT