

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

LUROAN 0.15% Single-Dose Eye Drops, Solution  
Sterile

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial (0.3 mL) contains:

**Active substance:**

Sodium hyaluronate.....0.45 mg

**Excipients:**

Disodium hydrogen phosphate dodecahydrate....0.168 mg

Sodium dihydrogen phosphate (anhydrous).....0.012

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/ Frequency and duration of administration

Unless otherwise recommended by the physician, it is recommended to instill 1 drop into the eye up to 6 times a day.

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.
- Hands should be washed before applying the medicine.
- Before use, the single-dose vials should be checked to ensure that they are not damaged or opened.
- A single-dose vial should be removed by pulling, and the tip of it should be opened by twisting.
- Once the single-dose vial is opened, it should be used immediately and any solution remaining after use should be discarded.
- While applying the medicine, the tip of the container should not be touched by any other surface, including the eyes or hands.

##### 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.

**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 0.054 mg of phosphate per vial.

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 (unless recommended by a doctor).

**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 ( $\geq 1/10$ ); common ( $\geq 1/100$  to  $< 1/10$ ); uncommon ( $\geq 1/1,000$  to  $< 1/100$ ); rare ( $\geq 1/10,000$  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**

No intraocular absorption occurs after application. 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. Most of sodium hyaluronate is metabolized in the liver. Here, this polysaccharide is metabolized into subunits, which will involve in other metabolic processes. Sodium hyaluronate is largely eliminated (70%) as CO<sub>2</sub> during respiration, while a small portion (22%) is excreted in the urine.

Absorption:

No intraocular absorption occurs after administration into conjunctival sac.

Distribution:

If injected into anterior chamber, polymer is rapidly eliminated through eye fluid circulation.

Biotransformation:

Sodium hyaluronate is metabolized in the liver.

Elimination:

Sodium hyaluronate is largely eliminated (70%) as CO<sub>2</sub> 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**

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 opening, use it immediately and discard the vial.

### **6.4 Special precautions for storage**

Store at room temperature below 25°C.

After the sachets are opened, the vials inside should be used within 10 days. During this period, the medicine can be stored at room temperature below 25°C.

### **6.5 Nature and contents of the container**



Transparent, low-density polyethylene disposable vials are used as packaging material for this medicinal product. The product is presented in a cardboard box with 2 sachets each containing 10 single-use vials, together with a 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**

DEVA Holding A.Ş.

Halkalı Merkez Mah. Basın Ekspres Cad. 34303 No:1

Küçükçekmece – İSTANBUL / TÜRKİYE

Tel: +90 212 692 92 92

Fax: +90 212 697 00 24

#### **8. MARKETING AUTHORIZATION NUMBER**

2018/566

#### **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**