



## PACKAGE LEAFLET

### **LUROAN 0.15% Single-Dose Eye Drops, Solution**

**Instilled into the eyes.**

**Sterile**

**Active substance:** Each vial (0.3 ml) contains 0.45 mg sodium hyaluronate.

**Excipients:** Disodium hydrogen phosphate dodecahydrate, sodium dihydrogen phosphate (anhydrous), sodium chloride, sodium hydroxide, hydrochloric acid, water for injections.

**Read all of this LEAFLET carefully before you start using this medicine because it contains important information for you.**

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *When you visit a doctor or hospital while using this medicine, tell them that you are using this medicine.*
- *Please follow the instructions in this leaflet. Do not use any **higher** or **lower** doses than the recommended dose of this medicine.*

#### **In this leaflet:**

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### **1. WHAT LUROAN IS AND WHAT IT IS USED FOR**

LUROAN is ready-to-use, clear and colorless, sterile eye drops in transparent, low-density polyethylene disposable vials.

LUROAN is used for the symptomatic treatment of dry eye disease.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU USE LUROAN**

#### **DO NOT USE LUROAN in the following conditions**

Do not use LUROAN if you are hypersensitive to the active substance or any of its excipients.

#### **USE LUROAN WITH SPECIAL CARE in the following conditions**

Do not use it together with other eye solutions that have detergent or disinfectant effects.

If these warnings apply to you, even at any time in the past, please consult your doctor.

#### **Using LUROAN with food and drink**

There is no interaction with food or drinks in terms of route of administration.

#### **Pregnancy**

*Ask your doctor or pharmacist before using this medicine.*

During pregnancy, LUROAN should be used only if required and under strict medical control.

*If you notice you are pregnant during treatment, tell your doctor or pharmacist immediately.*

### **Breastfeeding**

*Ask your doctor or pharmacist before using this medicine.*

The effect of LUROAN during breastfeeding is unknown.

### **Driving and using machines**

LUROAN has no effect on your ability to drive or use machines.

### **Important information about some of the excipients of LUROAN**

No adverse effects due to the excipients are expected unless you have hypersensitivity to the excipients of LUROAN. No warning is required for any of the excipients contained in this medicinal product due to the route of application or dosage.

### **Using with other medicines**

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

*Please inform your doctor or pharmacist if you are currently taking or have recently taken any other medicines, including those obtained without a prescription.*

## **3. HOW TO USE LUROAN**

### **Instructions for appropriate use and dose/frequency of administration**

Always use LUROAN exactly as your doctor has told you. The duration of treatment with LUROAN should be determined by the physician depending on the response to treatment. Unless your doctor recommends otherwise, instill 1 drop in each eye up to 6 times a day. This allows you to get the full benefit of LUROAN.

### **Route and method of administration**

For ophthalmic use only.

Applied to the eyes.

Wash your hands before applying the medicine.

Check that the single-dose vial is not damaged or opened before use.

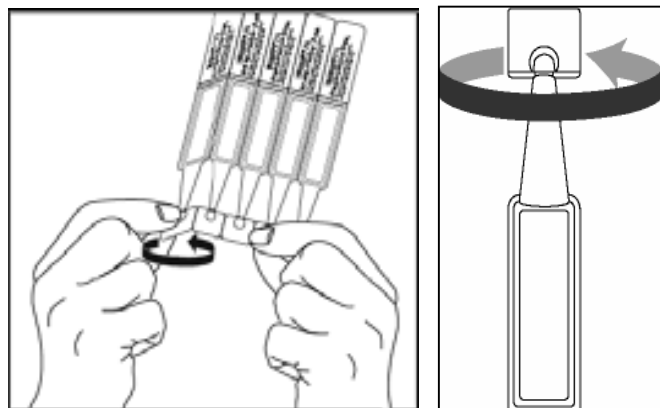
While applying the medicine, avoid contact of the tip of the vial with any surface, including your eyes and hands.

The solution in each vial is applied to one or both eyes immediately after opening for use.

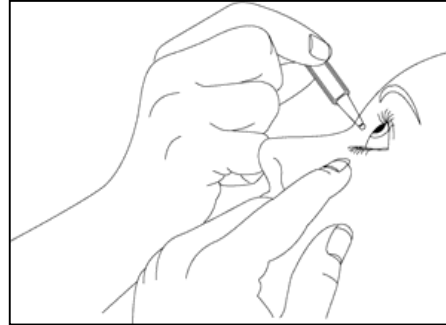
After a vial is opened, sterility cannot be maintained and the remainder should be discarded immediately after use.

### **Instructions for use**

1. Open the sachet containing the single-dose vials.
2. Break the tip of a vial and rotate it as shown.
3. Tilt your head back and gently pull down the lower eyelid to create a sac between the eye and eyelid as shown in the figure.
4. Instill 1 drop to the affected eye(s) as told by your doctor. Each vial contains enough drops for both eyes.



5. To avoid contamination, discard the used vial even if some solution remains after instillation.
6. Store the unused vials in its sachet. The vials that have not yet been used should be used within 10 days after opening the sachet. The vials remaining unused 10 days after opening the sachet should be discarded and a new sachet opened. It is important to use the eye drops prescribed by your doctor.



### **Different age groups**

#### Use in children

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

#### Use in the elderly

No special dose adjustment is required in the elderly.

### **Special conditions for use**

#### Kidney/Liver failure

There is no special use in patients with kidney/liver failure other than the dose recommended by the doctor.

Follow these instructions unless your doctor recommends otherwise.

*If you have an impression that the effect of LUROAN is too strong or too weak, talk to your doctor or pharmacist.*

### **If you use more LUROAN than you should**

No cases of overdose have been reported.

*If you have used more LUROAN than you should, please talk to your doctor or pharmacist.*

### **If you forget to use LUROAN**

If you forget to apply a dose of LUROAN, continue the treatment as usual in the morning of the next day.

*Do not take a double dose to make up for a forgotten dose.*

### **Possible effects if you stop using LUROAN**

Continue using LUROAN as long as your doctor prescribes it.

Do not stop your treatment without consulting to your doctor.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, LUROAN may cause side effects in people with sensitivity to its ingredients.

### **Tell your doctor if you notice any of the following:**

- Inflammation of the eyelid or conjunctiva
- Redness, increased tear secretion or superficial allergic reactions, keratitis
- Itching, burning



These are mild side effects of LUROAN. Mild side effects occur rarely.

*If you experience any side effects not listed in this leaflet, please inform your doctor or pharmacist.*

#### Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

#### **5. HOW TO STORE LUROAN**

*Keep LUROAN out of the reach and sight of children in its original package.*

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.

#### **Use in line with the expiry date.**

*Do not use LUROAN after the expiry date specified on the package.*

The first two digits on the label and box refer the month, and the last four digits refer the year. Do not use LUROAN if you notice defects in the product and/or package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### ***Marketing authorization holder:***

Deva Holding A.Ş.  
Küçükçekmece – İSTANBUL / TÜRKİYE

#### ***Manufacturing site:***

Deva Holding A.Ş.  
Kartepe – KOCAELİ / TÜRKİYE

*This package leaflet was approved on 10/10/2018.*