



## PACKAGE LEAFLET

### DUPATIN 0.1% Eye Drops, Solution Instilled into the eye(s) Sterile

**Active substance:** Each 1 mL solution contains olopatadine hydrochloride equivalent to 1 mg olopatadine.

**Excipients:** Benzalkonium chloride, sodium chloride, dibasic sodium phosphate dodecahydrate, hydrochloric acid, sodium hydroxide, water for injection.

**Read all of this PACKAGE 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, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the period when you take this medicine, tell your doctor that you take this drug when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or a **lower** dose other than recommended to you for this medicine.*

#### **In this leaflet**

- 1. What DUPATIN is and what it is used for**
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#### **1. WHAT DUPATIN IS AND WHAT IT IS USED FOR**

DUPATIN is an eye drop product presented in a 5 mL dropper bottle with a screw cap. It is a particle-free, clear, colorless solution. DUPATIN contains olopatadine as the active substance.

DUPATIN is used to treat the ocular signs and symptoms of seasonal allergic conjunctivitis.

**Allergic conjunctivitis:** Some materials (allergens) like pollens, house dust or animal fur may cause allergic reactions resulting in itching, redness as well as swelling of your eye surface.

DUPATIN is a medicine for treatment of allergic conditions of the eye. It works by reducing the intensity of the allergic reaction.

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

##### **DO NOT USE DUPATIN in the following situations:**

- Do not use DUPATIN if you are hypersensitive (allergic) to olopatadine or other ingredients contained in DUPATIN. Ask your doctor first.

##### **USE DUPATIN CAREFULLY in the following situations:**

- Do not use DUPATIN in children under 3 years of age.
- Remove your lenses from your eyes before using DUPATIN.

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

#### **Using DUPATIN with food and drinks**

It does not interact with food or drinks.

### **Pregnancy**

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

If you are pregnant or might become pregnant, consult your doctor before using this medicine.

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

### **Breastfeeding**

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

If you are breastfeeding, do not use DUPATIN as it may pass into your milk.

### **Driving and using machines**

You may find that your vision is blurred for a time just after you use DUPATIN. Do not drive or use machines until this has worn off.

### **Important information regarding some ingredients in DUPATIN**

DUPATIN contains a preservative (benzalkonium chloride) that may cause eye irritation. Avoid contact of the medicine with soft contact lenses. Remove contact lenses before instillation and wait at least 15 minutes after instillation to put the lenses back on. This preservative is known to cause discoloration of soft contact lenses.

This medicine contains 1 mg benzalkonium chloride per 5 ml that is equivalent to 0.2 mg/ml.

### **Using with other medicines**

If you are using other eye drops or eye ointment medicines, leave at least 5 minutes between each medicine. Eye ointments should be applied last.

*Please inform your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.*

## **3. HOW TO USE DUPATIN**

Always strictly follow your doctor's instructions while using DUPATIN. If you are not sure about the use of the medicine, check with your doctor or pharmacist.

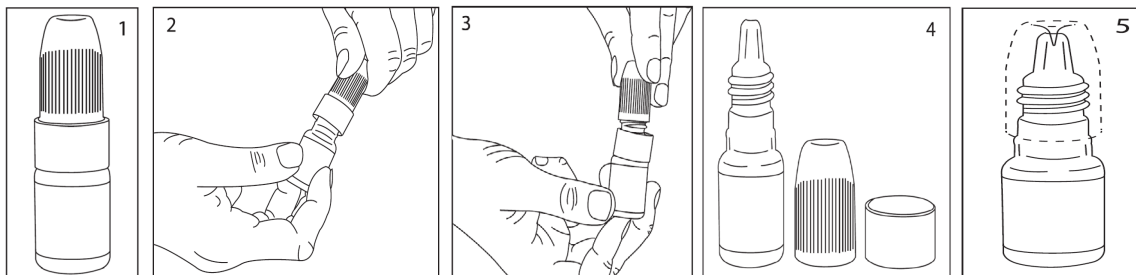
### **Instructions for proper use and dose/frequency of administration**

- Instill 1 drop into the affected eye(s), twice a day, morning and evening.
- Instill the prescribed dose unless otherwise recommended by the doctor.
- Instill DUPATIN in both eyes only if your doctor told you to.
- Instill DUPATIN for as long as your doctor told you.

### **Method and route of administration**

DUPATIN should only be used as an eye drop.

Wash your hands before instillation.



- Open the cap of the bottle.
- Remove the ring located under the cap (see Figure 3 and Figure 4).
- Close the cap again without the ring. The plastic pin inside the cap will puncture the tip of the bottle (see Figure 5).

Apply the medicine to your eyes as described below:

1. Tilt your head back. Gently pull your lower eyelid downwards with a hand, forming a pocket between your eye and eyelid.
2. With your other hand, hold the bottle upside down, vertically above your eye. Instill 1 drop squeezing slightly. Be careful not to touch the tip of the dropper to your hand or eyes.
3. After instillation, press the inner corner of your eye with your fingertip for about 1-2 minutes. This prevents the medicine from flowing into the nose through the tear ducts.



### **Different age groups**

#### Use in children

DUPATIN should not be used in children under 3 years of age.

#### Use in elderly

The use of the medicine for the elderly is the same as for adults.

### **Special conditions for use**

There are no special conditions for use.

### **If you used more DUPATIN than you should**

Rinse your eyes with warm water. Do not instill any more drops until your next regular dose.

*If you have used more DUPATIN than you should, contact a doctor or pharmacist.*

### **If you forget to use DUPATIN**

Instill a single dose as soon as you remember and continue with your regular dosing schedule. However, if it is almost time for your next dose, skip the missed dose and continue your regular dosing routine.

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

If you are using other eye medications, leave 5 to 10 minutes between consecutive applications.

### **Possible effects when treatment with DUPATIN is stopped**

No effects are expected. Do not stop using this medicine without consulting your doctor.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, DUPATIN can cause side effects in people with allergy to its ingredients.



**If any of the following occur, stop using DUPATIN and IMMEDIATELY inform your doctor or go to the emergency department of the nearest hospital:**

- Allergic reactions can vary from local itching or skin redness to severe allergic reactions (anaphylactic reactions - swelling, itching and redness that may occur throughout the body, throat congestion, shortness of breath, cough, dizziness, fainting, seizures, loss of consciousness, weak pulse, palpitations, irregular heartbeat and low blood pressure) or severe skin reactions.

These are all very serious side effects. If you have any of these, it means you are seriously allergic to DUPATIN. You may require urgent medical attention or hospitalization.

Side effects are listed as shown in the following categories:

Very common	: may affect at least 1 in 10 patients.
Common	: may affect less than 1 in 10 patients but more than 1 in 100 patients.
Uncommon	: may affect less than 1 in 100 patients, but more than 1 in 1,000 patients.
Rare	: may affect less than 1 in 1,000 patients.
Very rare	: may affect less than 1 in 10,000 patients.
Not known	: frequency cannot be estimated from the available data.

**Tell your doctor if you experience any of the following:**

**Common side effects**

- Headache
- Taste disorder
- Eye pain
- Eye irritation
- Dry eyes
- Abnormal eye sensation
- Dry nose
- Fatigue

**Uncommon side effects**

- Headache
- Inflammation in the nose (rhinitis)
- Dizziness
- Decrease in sensitivity
- Corneal erosion
- Corneal epithelium defect
- Corneal epithelium disorder
- Punctate keratitis (punctate inflammation in the transparent layer of the eye)
- Keratitis (inflammation of the transparent layer of the eye)
- Corneal spots
- Eye discharge
- Sensitivity to light
- Blurry vision
- Decrease in visual sharpness
- Spasm of eyelids
- Eye discomfort
- Itching of the eye



- Conjunctival follicles
- Conjunctival disorder
- Foreign body sensation in eyes
- Increase in tear production
- Itching of the eyelids
- Edema of the eyelids
- Eyelid disorders
- Redness of the eyelids
- Bloodshot eyes
- Contact dermatitis (an inflammatory skin disease that occurs through contact)
- Heat sensation on the skin
- Dry skin

**Not known**

- Increased sensitivity
- Swelling of the face
- Drowsiness
- Corneal edema
- Edema of the eye
- Swelling in the eye
- Conjunctivitis
- Increased pupil size
- Visual disorders
- Crusting of the eyelid
- Shortness of breath
- Infection of the sinuses (cavities in the nose and bones around the eyes)
- Nausea
- Vomiting
- Dermatitis (an inflammatory skin disease)
- Redness of the skin
- Weakness
- Malaise

These are mild side effects of DUPATIN.

Generally, you can continue using your medicine as long as these symptoms are not serious.

Very rare cases of corneal calcification (calcification in the transparent part of the eye) have been reported in association with the use of phosphate-containing eye drops in some patients with significant damage in their corneas (transparent front part of the eye).

*If you get any side effect not mentioned in this package leaflet, 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 DUPATIN**

*Keep DUPATIN out of the reach and sight of children and in its original package.*  
Store below 25°C at room temperature.

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

*Do not use DUPATIN after the expiry date stated on the package.*

Keep your bottle tightly closed after use.  
Once the bottle is opened, the product should be used within 28 days.

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

### **Manufacturer**

DEVA Holding A.Ş.  
Kartepe – KOCAELİ / TÜRKİYE

*This package leaflet was last approved on 12/02/2024.*