



PACKAGE LEAFLET

DUPATIN 0.2% Eye Drops, Solution
Instilled into the eye(s)
Sterile

Active substance: Each mL contains 2.22 mg olopatadine hydrochloride equivalent to 2 mg olopatadine.

Other ingredients: Benzalkonium chloride, hydroxyethyl cellulose, sodium chloride, edetate disodium, dibasic sodium phosphate anhydrous, concentrated hydrochloric acid and sodium hydroxide (pH adjuster), 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 **lower** dose other than recommended to you for this medicine.*

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1. WHAT DUPATIN IS AND WHAT IT IS USED FOR

DUPATIN is an eye drop presented in an opaque, white colored, low density polyethylene (LDPE) bottle with a white colored, twist off polypropylene cap. It is clear to light yellow solution.

DUPATIN is used for prevention and treatment of ocular signs and symptoms that occur as a result of allergic conjunctivitis.

Allergic conjunctivitis: Some substances (allergens) such as pollens, house dust or animal fur can cause redness or severe itching as well as swelling on the eye surface.

DUPATIN is an anti-allergic drug used for treatment of allergic conditions of the eye. It reduces the intensity of allergic reactions.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DUPATIN

Do not use DUPATIN:

- If you are hypersensitive (allergic) to olopatadine or any of the other ingredients in DUPATIN.



Use DUPATIN carefully in the following situations:

- If you wear contact lenses. DUPATIN should not be used while wearing lenses.
- Do not use DUPATIN in children under 3 years of age.

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

Using DUPATIN with food and drinks

If the product is used as recommended, it will have no interaction with food or drink.

Pregnancy

Consult your doctor or pharmacist before using this drug.

There are no adequate studies on the use of the drug in pregnant women, therefore caution should be exercised when using it during pregnancy. DUPATIN should only be used when absolutely necessary.

During your treatment, if you realize that you're pregnant, consult to your doctor or pharmacist immediately.

Breastfeeding

Consult your doctor or pharmacist before using this drug.

Do not use DUPATIN if you are breast-feeding, it may pass into your breast-milk.

Driving and using machines

You may notice that your vision is blurred for a while just after using DUPATIN. Do not drive or use machinery until this situation wears off.

Important information regarding some ingredients in DUPATIN

DUPATIN contains benzalkonium chloride. This may result in eye irritation. Avoid contact of the drug with soft lenses. Remove the contact lens before application and wait at least 15 minutes to insert the lens.

It is known to cause discoloration of soft contact lenses.

Using with other medicines

If you are using another eye drop or eye ointment medicines, wait at least 5 minutes between each application. Eye ointments should be administered last.

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

3. HOW TO USE DUPATIN

Always use DUPATIN exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Instructions for proper use and dose/frequency of administration

- One drop is instilled into the eye affected by allergic conjunctivitis, once a day.
- Unless recommended otherwise by the doctor, use the specified doses.
- Use DUPATIN in both eyes only if your doctor tells you to.
- Use DUPATIN for as long as your doctor has told you.

Method and route of administration

DUPATIN should only be used as an eye drop.



1. Take the DUPATIN bottle and a mirror.
2. Wash your hands.
3. Open the cap of the bottle.
4. Hold the bottle with your thumb and other fingers with the tip of the bottle pointing down (Figure 1).
5. Tilt your head back (Figure 2).
6. With the help of a clean finger, pull your eyelid down until a pocket is formed between your eye and eyelid. The drop will go in here (Figure 3).
7. Bring the tip of the dropper close to your eye. Use the mirror if it helps.
8. Do not touch your eye, eyelid, surrounding areas other surfaces with the dropper. It could contaminate the drops.
9. Gently press on the base of the dropper bottle to release one drop of DUPATIN eye drops at a time.
10. Do not squeeze the dropper bottle; it is designed so that just a gentle press on the bottom is needed (Figure 2).
11. If you use drops in both eyes, repeat the steps for your other eye.
12. Put the dropper bottle cap back on firmly immediately after use.
13. For each treatment period, use a new bottle.

If a drop misses your eye, try again.

Different age groups

Use in children:

Do not use DUPATIN in children under 3 years of age.

Use in elderly:

Use in the elderly is the same as in adults.

Special conditions for use

There is no special condition for use.

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

If you used more DUPATIN than you should

Rinse your eyes with warm water. Do not instill any more drops until it's the time for your next regular dose.

Talk to a doctor or pharmacist if you have used more DUPATIN than you should.



If you forget to use DUPATIN

Use a single drop as soon as you remember..

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

If you are using another eye medication, leave 5 to 10 minutes between consecutive applications.

Possible effects when treatment with DUPATIN is stopped There are no expected effects.

4. POSSIBLE SIDE EFFECTS

Like all medicines, side effects can occur in people who are sensitive to the ingredients of DUPATIN.

Very common: may occur in at least 1 in 10 patients.

Common: may occur in less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: may occur in less than 1 in 100 patients, but more than 1 in 1,000 patients.

Rare: may occur in less than 1 in 1,000 patients.

Very rare: may occur in 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

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

Uncommon

- Headache
- Inflammation in the nose (Rhinitis)
- Dizziness
- Decrease in sensitivity
- Corneal erosion
- Corneal epithelium defect
- Corneal epithelium disorder
- Punctate keratitis (inflammation of small groups of cells on the surface of the cornea)
- 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 (inflammatory skin disease caused by 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.

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 corneal (transparent part of the eye) damage.

If you experience any side effect not mentioned in this 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 store it in its package.

Store below 25°C at room temperature.

Use in accordance with the expiry date.

Do not use DUPATIN after the expiry date which is 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.

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