

## PATIENT INFORMATION LEAFLET

### CONJITEN 0.025% sterile eye drop

Apply to the eyes

- **Active substance** : Each 1 mL solution contains 0.25 mg ketotifen (equivalent to 0.345 mg ketotifen hydrogen fumarate)
- **Excipients** : Benzalkonium chloride, glycerol, sodium hydroxide, hydrochloric acid, water for injection

**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, ask your doctor or pharmacist.*

*This medicine has been prescribed for you only. Do not pass it on to others.*

*Tell your doctor if you go to a doctor or a hospital when you are using this medicine.*

*Follow these instructions exactly. Do not use **high or low** doses other than the recommended dose for the drug.*

### What is in this leaflet

1. **What CONJITEN is and what it is used for**
2. **What you need to know before you use CONJITEN**
3. **How to use CONJITEN**
4. **Possible side effects**
5. **How to store CONJITEN**

#### 1. What CONJITEN is and what it is used for ?

CONJITEN contains 0.25 mg ketotifen (as 0.345 mg ketotifen hydrogen fumarate) in each mL of solution as active ingredient.

CONJITEN is a clear, colourless or pale yellow solution and is available as 5 ml bottles containing solution.

CONJITEN is a part of group of drugs used allergy. It is used in the treatment of itching and redness, occurs in the eyes due to allergy.

#### 2. What you need to know before you use CONJITEN

## **Do not use CONJITEN**

- If you have hypersensitivity to ketotifen or any compound present in the formulation of CONJITEN (see excipients list )

## **Use CONJITEN WITH CAUTION in the following conditions**

- If you are using contact lenses - CONJITEN contains a substance that can accumulate in soft contact lenses called benzalkonium chloride; therefore, there should't be contact lenses on eye during application of the drug. All eye drops containing benzalkonium chloride may fade the color of soft contact lenses.

*If you have ever had any of these conditions, tell your doctor before you use CONJITEN*

## **CONJITEN with food and drink**

There is no interaction with food and drink due to the way of use

## **Pregnancy**

*Consult your doctor or pharmacist before using the medicine*

Do not use CONJITEN during pregnancy unless your doctor sees it necessary.

*Consult your doctor or pharmacist if you notice that you are pregnant during treatment.*

## **Lactation**

*Consult your doctor or pharmacist before using the medicine*

Do not use CONJITEN during lactation unless your doctor sees it necessary.

## **Effects on ability to drive and use machines**

CONJITEN will cause blurred vision or drowsiness, in this cases do not use vehicles and machinery.

## **Important information about some of the excipients present in CONJITEN**

CONJITEN contains benzalkonium chloride as a preservative and it can cause. Eye irritation. Avoid contact with the soft contact lenses. Remove the contact lens before application and wait at least 15 minutes to attach the lens. All eye drops containing benzalkonium chloride may fade the color of soft contact lenses.

## **CONJITEN with other medicinal products**

If you are using other eye medications in addition to CONJITEN, wait at least five minutes between the application of two medications.

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

### **3.How to use CONJITEN ?**



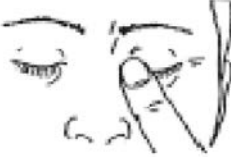
#### **Instructions for proper use and dose / application frequency:**

Apply 1 drop 2 times a day to your eye unless otherwise recommended by your doctor. Always follow your doctor's advice.

#### **Use of administration and method:**

Wash your hands before apply the drug.

Apply to your eyes as indicated below :

1. Tilt your head backwards; create a hole between your eye and eyelid by pulling your lower eyelid down gently with one hand.	
2. Hold on the bottle upside down with your other hand. Gently squeeze a drop. Be careful about not touch the tip of the dropper by hand or eye.	
3. After dripping press for 1-2 minutes with your fingertips. This prevents the flowing of the drug to the nose through the tear ducts.	

#### **Different age groups**

##### **Pediatric population :**

Safety and efficacy of CONJITEN have not been established in pediatric patients under 3 years of age. The dose in children over 3 years old is the same as for adults.

##### **Geriatric population :**

Dose adjustment is not necessary for geriatric population.

##### **Hepatic/renal failure :**

The efficacy and safety of CONJITEN in renal or hepatic insufficiency have not been studied.

*If you think that the effect of CONJITEN is very strong or weak talk to your doctor or pharmacist.*

**If you use more CONJITEN than you should :**

If you have used more CONJITEN, wash your eyes with warm water.

*If you use CONJITEN cream more than you need to use, talk to a doctor or pharmacist.*

**If you forget to use CONJITEN**

Apply the dose as soon as you remember and then continue with the regular application. Do not double-dose to compensate for forgotten doses.

**Effects that may occur when CONJITEN is discontinued**

Do not discontinue your treatment without consulting your doctor.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects if you have hypersensitivity to any compound present in the formulation

**If you have any of the following, stop using CONJITEN and IMMEDIATELY tell your doctor or contact the nearest hospital emergency department:**

- Allergic response, dry mouth

These are all very serious side effects. If you have one of these, you have serious allergies to CONJITEN. you may need immediate medical attention or hospitalization.

**If you notice any of the following, tell your doctor immediately or please contact the emergency department of the nearest hospital:**

- Eye bleeding
- Inflammation of the transparent body (cornea) of the eye

All these are serious side effects. Emergency medical intervention may be required.

**If you notice any of the following, tell your doctor:**

- Headache, sleepiness
- Eye burning / stinging
- Blurred vision, eye dryness, eyelid discomfort after application pain, light or light disturbance

These are slight side effects of CONJITEN.

*If you experience any side effects not mentioned in this patient information leaflet, inform your doctor or pharmacist.*

## Reporting of suspected adverse reactions

Talk to your doctor, pharmacist or nurse if you have any side effects located or not in patient information leaflet. In addition, notify the side effects you are experiencing to [www.titck.gov.tr](http://www.titck.gov.tr) site by clicking "Drug side effects notification" icon or by calling 0 800 314 00 08 numbered side effect statement line Turkey Pharmacovigilance Center (TÜFAM). By reporting side effects, you will contribute to learning more about the safety of the medicine you are using.

## **5. How to store CONJITEN ?**

*Keep CONJITEN out of the sight and reach of children, in its package.*

Store at room temperature below 25°C in original package.

Close the lid immediately after use.

Keep the bottle in its outer package to protect it from light.

The bottle should be used within 28 days after opening. Do not store the unused portion.

### **Use in accordance with expiration date**

*Do not use CONJITEN after the expiry date which is stated on the carton*

Do not use CONJITEN if you notice that the pack is damaged or show signs of tampering.

Do not throw away any expired or unused medicines! Give to the collection system determined by the Ministry of Environment and Urbanism

**Marketing Authorisation Holder :** Biem İlaç San. ve Tic. A.Ş.  
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Tandoğan / Çankaya – Ankara

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