



## PACKAGE LEAFLET: INFORMATION FOR THE USER

### OFTAMYCIN 0.3% Eye Drops, Solution

Instilled into the eye(s)

Sterile

**Active substance:** Each ml solution contains 3 mg tobramycin.

**Excipients:** Benzalkonium chloride, tyloxapol, sodium chloride, anhydrous sodium sulphate, boric acid, sodium hydroxide, sulfuric acid, 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 use this medicine 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.*

### **What is in this leaflet:**

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

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

OFTAMYCIN is used for the treatment of superficial bacterial infections in and around the eye(s).

OFTAMYCIN belongs to the group of drugs called anti-infectives. The anti-infectives group contains antibiotics (tobramycin in this product) which are active against a wide range of microorganisms that may infect the eye(s).

OFTAMYCIN is a clear and colorless solution. No particles should be observed.

The packaging material is an opaque white, low-density polyethylene dropper bottle containing 5 ml solution, sealed with an orange screw cap.

### **2. BEFORE YOU USE OFTAMYCIN**

#### **DO NOT USE OFTAMYCIN**

- If you are hypersensitive (allergic) to tobramycin or to any other ingredients of this medicine.
- If you are allergic to aminoglycosides.

#### **TAKE SPECIAL CARE WITH OFTAMYCIN**

- If you experience allergic reactions with OFTAMYCIN, discontinue use and consult your doctor. Allergic reactions may vary from localized itching or skin redness to severe allergic reactions (anaphylactic reaction) or serious skin reactions. These allergic reactions may occur with other topical (superficial) or systemic antibiotics of the same family (aminoglycoside type).

- Hypersensitivity to superficially (topically) applied aminoglycosides (antibiotics) may occur in some patients. Cross-sensitivity to other aminoglycoside class antibiotics may also occur. Stop the treatment if signs of severe allergic reactions occur.
- If you are using other antibiotic treatment along with OFTAMYCIN, ask your doctor for advice.
- When used together with systemic aminoglycoside antibiotic treatment, poisoning effects that may occur due to the accumulation of the product in the ear, kidney and nerves, such as ringing in the ear, hearing loss, dizziness, balance disorder, decrease in urine output, blood in the urine and swelling in the body, should be taken into consideration.
- If you have or if you have ever had conditions such as myasthenia gravis or Parkinson's disease, ask your doctor for advice. Antibiotics of this kind may worsen muscle weakness.
- As with any antibiotic, prolonged use may result in overgrowth of non-susceptible bacteria and fungi (organisms that develop drug resistance). If superinfection occurs (occurrence of a second infection in a body weakened by another infection) appropriate therapy should be initiated.
- Wearing contact lenses is not recommended while undergoing treatment for eye infection, as their use during treatment may worsen your current condition. Do not use contact lens while being treated with this product.
- OFTAMYCIN contains benzalkonium chloride as a preservative that may cause eye irritation and that is known to discolor soft contact lenses. Remove your contact lenses before applying OFTAMYCIN and wait 15 minutes before putting them back on.
- Use this medicine for as long as your doctor recommends.
- If your disease gets worse or symptoms reoccur, consult your doctor.
- If you are using other medicines, please read the section 'Using with other medicines'.

*If these warnings are applicable to you, even for any period of time in the past, please consult your doctor.*

### **Using OFTAMYCIN with food and drinks**

If the product is used as recommended, no interaction with food and drinks is expected.

### **Pregnancy**

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

Your doctor will decide on your treatment, otherwise the medicine should never be used unless strictly necessary.

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

### **Breast-feeding**

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

Your doctor will decide whether you can use OFTAMYCIN during breastfeeding or whether breastfeeding should be stopped.

### **Driving and using machines**

If you experience blurred vision after using OFTAMYCIN, do not drive or use machinery until your vision clears.

### **Important information about some of the ingredients of OFTAMYCIN**

OFTAMYCIN contains benzalkonium chloride. Therefore, the medicine may cause eye irritation.

Avoid contact of the medicine with soft contact lenses. Remove your contact lenses before application and wait at least 15 minutes before putting them back on.

The excipient is also known to discolor soft contact lenses.

### **Using with other medicines**

Concomitant and/or sequential use of an aminoglycoside (such as tobramycin) and other systemic, oral, or topical drugs that have toxic (harmful) effects on nervous system, ear or kidneys may increase these harmful effects. Such concomitant use should be avoided whenever possible.

If used concomitantly with other topical (superficial) eye medications, there should be an interval of 5-10 minutes between two applications. Eye ointments should be applied last.

Topical corticosteroids used in combination with OFTAMYCIN may mask the clinical signs of bacterial, fungal, or viral infections and may suppress hypersensitivity reactions.

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

## **3. HOW TO USE OFTAMYCIN**

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

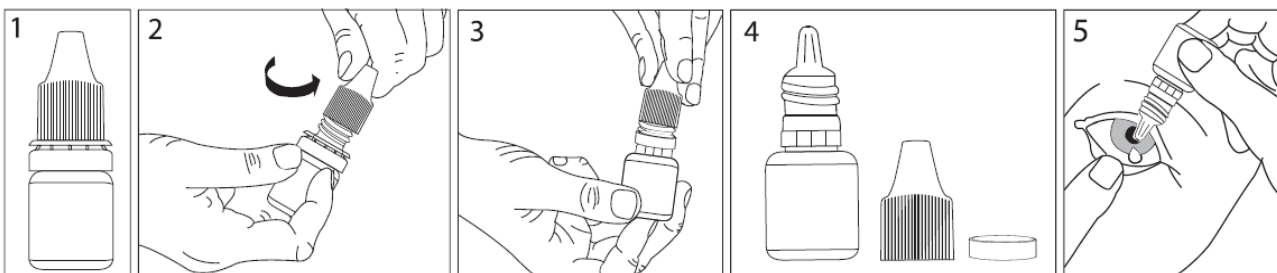
Always use OFTAMYCIN exactly as your doctor has told you. If you are not sure, consult your doctor or pharmacist.

In mild to moderate infections, the usual dose is 1 or 2 drops into the eye(s) every 4 hours for 7 days.

In severe infections, the usual dose is 2 drops hourly until improvement is achieved. Once improvement is achieved, the dose is reduced and then discontinued.

The normal treatment period is between 7 to 10 days. Your doctor will tell you how long your treatment period will last.

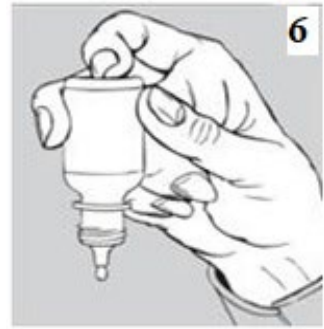
### **Route and method of administration**



Apply OFTAMYCIN only to your eyes.

- Get the OFTAMYCIN bottle and a mirror.
- Wash your hands.
- Twist off the bottle cap (see Figure 2).
- Remove the ring under the cap (see Figure 3 and Figure 4).

- Hold the bottle, pointing down, between your thumb and middle finger.
- Tilt your head back. Pull down your lower eyelid with a clean finger until there is a pocket between your eyelid and your eye. The drop will go in here. (see Figure 5)
- Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
- Do not touch your eye, eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.
- Gently press on the base of the bottle to release one drop from OFTAMYCIN at a time. (see Figure 6)
- After using OFTAMYCIN, release your eyelid, close your eye, place a finger on the inner corner of your eye and press it towards your nose. This prevents OFTAMYCIN from getting into the rest of the body. (see Figure 7)
- If you are using the drops in both eyes, repeat the same steps for your other eye.
- Close the bottle cap firmly immediately after use.
- Before opening another bottle, use one up completely.
- If a drop misses your eye, try again.



If you are using other medications such as eye drops or eye ointments, allow at least 5 minutes between each application. Eye ointments should be applied last.

### **Different age groups**

#### **Use in children**

There is no special use for children aged 1 year and above, the dose is the same as for adults. No efficacy and safety information is available for children under 1 year of age.

#### **Use in the elderly**

The use in elderly is the same as in adults.

### **Use in special conditions**

#### **Kidney/Liver failure**

The effects of OFTAMYCIN in kidney/liver failure are unknown. However, due to low systemic absorption of tobramycin after topical administration, no dose adjustment is necessary.

*If you think that the effect of OFTAMYCIN is too strong or too weak, talk to a doctor or pharmacist.*

#### **If you use more OFTAMYCIN than you should:**

Wash your eyes with lukewarm water. Do not drip another drop until next application time.

*Please talk to a doctor or pharmacist if you used more OFTAMYCIN than you should.*

#### **If you forget to use OFTAMYCIN:**

Apply a single dose when you remember. If the next application time is close, do not take the forgotten dose; continue to apply in your normal schedule.

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



**Possible effects when you stop using OFTAMYCIN:**

Your treatment will be insufficient if you interrupt the treatment before recommended time.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, side effects can be observed in patients who are sensitive to the ingredients of OFTAMYCIN.

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

- Hypersensitivity reactions may appear with symptoms such as itching or swelling of the eyelids and redness of the eyes. If the reaction is severe, it can turn into a life-threatening condition called anaphylactic reaction, which is accompanied by symptoms such as skin rash, hoarseness, difficulty swallowing, cough, shortness of breath, swelling of the face and tongue, palpitations and dizziness.

These are all very serious side effects. If you experience any of these, it means that you are severely allergic to OFTAMYCIN. You may need emergency medical attention or hospitalization.

Side effects are listed as shown in the following categories:

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

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

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

Rare : may occur in less than 1 in 1,000 but more than 1 in 10,000 patients.

Very rare : may occur in less than 1 in 10,000 patients.

Not known : cannot be estimated from the available data.

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

**Common**

- Eye discomfort
- Redness in the eyes
- Allergy in the eyes
- Eyelid itching

**Uncommon**

- Inflammation of the transparent layer of the eye (cornea)
- Corneal abrasion
- Redness of the eyelids
- Discharge from eyes
- Eyelid edema
- Dryness in the eyes
- Edema in the conjunctiva (a thin and transparent membrane covering the inner eyelids and the white part of the eyes [sclera])
- Itchy eyes
- Eye pain
- Visual impairment
- Hypersensitivity

- Headache
- Hives
- Dermatitis (a type of skin disease)
- Loss of eyebrows and eyelashes
- Leukoderma (light-colored patch-like spots on the skin)
- Itching
- Dry skin
- Blurred vision
- Increased lacrimation

#### **Not known**

- Irritation in the eyes
- Serious allergic reaction
- Serious skin reactions (Erythema multiforme, which is seen on the body as symmetrical target-like red rashes that are darker in the center and fading outwards; and also Stevens-Johnson syndrome, which is characterized by fever and widespread blisters on the body)
- Allergy in the eyes
- Itchy eyelids
- Skin redness

These are mild side effects of OFTAMYCIN. These mild side effects occur very 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 OFTAMYCIN**

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

Store below 25°C at room temperature.

Once the bottle is opened, this product should be used within 4 weeks (28 days). During this period, the product can be stored below 25°C at room temperature.

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

Do not use OFTAMYCIN after the expiry date that is stated on the package.

*Do not use OFTAMYCIN if you notice any defects in the product and/or its 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.



**OFTAMYCIN 0.3% Eye Drops, Solution**  
**Module 1.3.1 Package Leaflet**



***Marketing Authorization Holder:***

DEVA Holding A.Ş.  
Halkalı Merkez Mah. Basın Ekspres Cad. No:1  
34303 Küçükçekmece - ISTANBUL/TURKEY

***Manufacturing Site:***

DEVA Holding A.Ş.  
Kartepe – KOCAELI / TURKEY

*This package leaflet was approved on 16/08/2023.*