

**Erythromycin (Oftalmolosa Cusi Erythromycin 5 mg/g Ophthalmic Ointment)**  
**Notification to Healthcare Professionals Regarding Packaging and Leaflet Deficiency**  
**Date: 9/4/2025**

Dear Healthcare Professionals,  
Greetings,

With reference to the report received from one of the healthcare institutions regarding a packaging defect in Oftalmolosa 5 mg/g (Batch No. A10801), we would like to inform you of the following after reviewing the batch release data:

This information is being communicated in agreement with the Saudi Food and Drug Authority (SFDA).

**Nature of the Issue:**

It has been found that the outer packaging and patient information leaflet of the affected batch are written in a foreign language other than English or Arabic, and no versions in Arabic or English were provided. This is non-compliant with SFDA requirements for ensuring clarity of information for users.

**Actions Taken:**

- Coordination is ongoing with NUPCO to implement the necessary corrective actions.
- The patient information leaflet has been printed in English.
- Label stickers have been printed to provide the required information on the outer packaging.

**Recommendations:**

- All healthcare professionals are kindly requested to refer to the English version of the Patient Information Leaflet for this batch to ensure that all necessary information is clearly communicated for safe and effective use.
- If you require more details regarding this batch, please contact the company at 0562442566 or via email at [Regulatory@aodci.com.sa](mailto:Regulatory@aodci.com.sa).
- If you notice any packaging with unclear information for any other batch, please report it immediately to the SFDA reporting system: <https://ade.sfda.gov.sa/Home/Report>.

**Attachments:**

- Please refer to the Patient Information Leaflet provided in Annex 1.

**Call for Reporting**

If you experience any adverse events or have concerns related to *Oftalmolosa Cusi Erythromycin 5 mg/g Ophthalmic Ointment*, please report via:

- **Marketing Authorisation Holder (MAH):**  
NTC S.r.l.  
Via Luigi Razza, 3, 20124 Milan, Italy  
Tel: +39 02 438 5041 • Email (PV): [pharmacovigilance@ntcpharma.com](mailto:pharmacovigilance@ntcpharma.com).
- **National Pharmacovigilance Center (NPC) – Saudi Food & Drug Authority (SFDA):**  
Call Center: 19999  
Email: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)  
Website: <https://ade.sfda.gov.sa>

We appreciate your commitment to patient safety and quality care, and we thank you for your continued cooperation.

Sincerely,  
Arabian Oasis for Development and Commercial Investment Company



## ANNEX 1 Package leaflet: information for the user OFTALMOLOSA CUSÍ ERYTHROMYCIN 5 mg/g ophthalmic ointment erythromycin

**Read the entire package leaflet carefully before you start using this medicine because it contains information that is important to you.**

- Keep this leaflet, as you may have to re-read it.
- If you have any questions, ask your doctor or pharmacist.
- This medicine is prescribed only for you and you should not give it to other people even if they have the same symptoms as you because it may harm them.
- If you experience any side effects, consult your doctor or pharmacist, even if they are side effects that are not listed in this leaflet. See section 4.

### Package Insert Contents

- 1- What is OFTALMOLOSA CUSÍ ERYTHROMYCIN and what is it used for?
- 2- What you need to know before you start using OFTALMOLOSA CUSÍ ERYTHROMYCIN
- 3- How to use OFTALMOLOSA CUSÍ ERYTHROMYCIN
- 4- Possible side effects
- 5- Storage of OFTALMOLOSA CUSÍ ERYTHROMYCIN
- 6- Contents of the package and additional information

### 1. What is OFTALMOLOSA CUSÍ ERYTHROMYCIN and what is it used for?

It is an ophthalmic ointment (for the eyes) that contains an antibiotic (erythromycin), which acts against certain microorganisms that cause infection in the eyes.

**Antibiotics are used to treat bacterial infections and are not used to treat viral infections. It is important that you follow the instructions for dosage, interval of administration and duration of treatment given by your doctor. Do not store or reuse this medication. If you have any antibiotic left over after the treatment is finished, return it to the pharmacy for proper disposal. You should not throw medicines down the drain or in the trash.**

This medication is used to treat superficial eye infections caused by erythromycin-sensitive organisms; and as a preventive treatment for ophthalmia in the newborn (neonatal conjunctivitis).

### 2. What you need to know before you start using OFTALMOLOSA CUSÍ

#### Do not use Ophthalmolose Cusi Erythromycin

If you are allergic to erythromycin or any of the other ingredients of this medicine (listed in section 6).

#### Warnings and Precautions

Talk to your doctor or pharmacist before using Ophthalmolose Cusi Erythromycin.

Only use this medication in your eye(s).

If you use this medication for a long period of time or in excess, you may become more sensitive to other eye infections, including fungal infections. Call your doctor if your symptoms get worse or come back suddenly.

**If you wear contact lenses:**

- Wearing contact lenses (hard or soft) is not recommended during the treatment of an eye infection.

**Other Medications and Ophthalmolose Cusi Erythromycin**

tell your doctor or pharmacist if you are using, have recently used, or may need to use any other medications.

**Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you might be pregnant, or intend to become pregnant, talk to your doctor or pharmacist before using this medicine. This medication is not recommended during pregnancy.

During breastfeeding, it should be decided whether it is necessary to interrupt breastfeeding or to discontinue treatment with this medicinal product after considering the benefit of breastfeeding for the child and the benefit of treatment for the mother.

**Driving and using machines**

You may notice blurred vision immediately after application of Ophthalmolose Cusi Erythromycin. Do not drive or use machines until this effect has worn off.

**3. How to use OFTALMOLOSA CUSÍ ERYTHROMYCIN**

Follow the instructions for taking this medication exactly as directed by your doctor. If in doubt, consult your doctor or pharmacist again.

The recommended dosage is:

**Adults and children**

In the treatment of superficial eye infections: Apply approximately 1cm of ointment to the affected eye(s) one or more times a day, depending on the severity of the infection (up to a maximum of 6 times a day).

**Newborn**

A single application is sufficient in the preventive treatment of ophthalmia in the newborn.

**Recommendations for use:**

- Wash your hands and stand in front of a mirror.
- Take the tube of ointment.
- **If the application is inside the eye**, spread the eyelid down with a clean finger.  
Apply the ointment to the pouch that forms between your eyelid and eye.
- **If the application is outside the eye**, apply the ointment to the affected part directly, previously removing the scabs by softening them with warm water.
- Place the tip of the tube near your eye. The mirror can be useful to you.

- Avoid touching the tip of the tube to your eye, eyelid, surrounding eyelid, or any other surface.
- Gently press the tube to let the ointment come out.
- Close the eye(s) for a few seconds after applying the ointment.
- Close the tube tightly after use.

**If you are using other ophthalmic medications**, wait at least 5 minutes between giving this ointment and the other ophthalmic medications. Ophthalmic ointments should be administered last.

**If you use more Ophthalmolose Cusi Erythromycin than you should**

An overdose on the eyes can be eliminated by washing the eyes with warm water. Do not apply more ointment until your next dose.

In case of overdose or accidental ingestion, consult your doctor or pharmacist immediately or call the Poison Control Service. Telephone 91 562 04 20, indicating the medicine and the amount used.

**If you forget to use Ophthalmolose Cusi Erythromycin**

Do not give yourself a double dose to make up for missed doses.

Apply it as soon as you notice it and continue with the next dose that was planned. However, if it is almost time for your next dose, skip the missed dose and continue with the next dose of your usual regimen.

If you have any other questions about using this medication, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

The following adverse reactions of unknown frequency (*cannot be estimated from the available data*) have been observed with this medicine:

General effects: allergy (hypersensitivity), mild eye irritation and redness; burning sensation.

**Reporting of adverse effects**

If you experience any side effects, consult your doctor or pharmacist, even if they are possible side effects that are not listed in this leaflet. You can also report them directly through the Spanish Pharmacovigilance System for Medicinal Products for Human Use: [https:// www.notificaram.es](https://www.notificaram.es). By reporting side effects you can help provide more information about the safety of this medicine.

## 5. Storage of OFTALMOLOSA CUSÍ ERYTHROMYCIN

- Keep this medication out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the tube and carton after EXP. The expiry date is the last day of the month indicated.
- Do not store at a temperature higher than 25°C.
- To avoid infection, you should throw away the tube 4 weeks after you first open it. Enter the date the tube was opened in the box reserved for this purpose in the box.
- Medicines should not be thrown down the drains or in the trash. Deposit the containers and medicines you do not need at the SIGRE Point of the pharmacy. If in doubt, ask your pharmacist how to dispose of containers and medicines you do not need. In this way, you will help protect the environment.

## 6. Contents of the package and additional information

- The active substance is erythromycin. Each gram of ointment contains 5 mg of erythromycin (0.5%).
- The other ingredients are cholesterol, liquid paraffin and white petroleum jelly.

### Product appearance and packaging contents

Ophthalmolose Cusí Erythromycin is an ophthalmic ointment (for use in the eyes), whitish, which comes in an aluminum tube containing 3.5 g with a polyethylene cap.

### Marketing authorisation holder:

NTC S.r.l.  
Via Luigi Razza, 3  
20124 Milán, Italy

### Manufacturing Manager

Siegfried El Masnou, S.A.  
C/ Camil Fabra, 58  
08320 El Masnou – Barcelona, Spain.

You can request more information regarding this medicine by contacting the local representative of the marketing authorisation holder:

NTC Ophthalmics Ibérica, S.L.  
Calle Pinar 5  
28006 Madrid, Spain

**Date of last revision of this prospectus:** January 2020.

Detailed information on this medicine is available on the website of the Spanish Agency for Medicines and Health Products (AEMPS) <http://www.aemps.gob.es>

