1. NAME OF THE MEDICINAL PRODUCT
OFTALMOLOSA CUSI® Antiedema 50 mg/g eye ointment

2. QUALITATIVE AND QUANTITAVE COMPOSITION
1 gram of ointment contains 50 mg of sodium chloride.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Eye ointment.
Yellowish homogeneous ointment

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Reduces the corneal edema, which may be due to a variety of factors such as bullous keratitis, post-operative of cataract extraction and hereditary corneal dystrophia or Fuch's dystrophia.

4.2 Posology and method of administration
Posology
Normally it is applied 1 or 2 times a day. The number of daily applications and the duration of treatment could be modified according to physician's criterion.

Pediatric population
The safety and efficacy of Sodium Chloride in children have not yet been established. Its use is currently not recommended in pediatric patients until data have become available regarding its safety and efficacy.
The product should be kept out of the reach of children.

Method of administration
For ocular use only
To prevent contamination, care must be taken not to touch the eyelids, surrounding areas, or other surfaces with the tip of the tube. Instruct patients to keep the tube tightly closed when not in use.
If more than one topical ophthalmic medicinal product is being used, the medicinal products should be administered at least 5 minutes apart. Eye ointments should be administered last.
Separate the eyelids from the eye and apply an amount of ointment equivalent to a grain of rice into the conjunctival sac.Application of ointment should be carried out under hygienic conditions, avoiding contact with the nozzle of the tube.Close tube after every application

4.3 Contraindications
• Hypersensitivity to any component of the product.

4.4 Special Warnings and precautions for use
• This product contains methylparahydroxybenzoate and propylparahydroxybenzoate as preservatives which may cause allergic reactions (possible delayed).
This product contains wool fat which may cause local skin reactions (e.g. contact dermatitis)
Keep all medication out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction
No clinically relevant interactions have been described.

4.6. Fertility, pregnancy and lactation

Fertility

Studies have not been performed to evaluate the effect of ocular administration of sodium chloride on male or female fertility. No animal fertility studies have been conducted Sodium chloride administered by the topical ocular route would not be expected to have any effect on fertility.

Pregnancy

There are no or limited amount of data from the use of ophthalmic sodium chloride in pregnant women. Sodium chloride administered by the topical ocular route would not be expected to elicit reproductive toxicity.

Lactation

There is no adequate data regarding the impact of sodium chloride eye drops/ointment on lactation or on the breast-fed infant. Used as directed, no effects on the breastfed newborn/infant are anticipated following topical ocular administration of sodium chloride.

4.7. Effects on ability to drive and use machines

Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs after administration, the patient must wait until the vision clears before driving or using machinery.

4.8 Undesirable Effects

The following adverse reactions have been reported following administration of OFTALMOLOSA CUSI Antiedema Eye Ointment. Frequency cannot be estimated from the available data.

System Organ Classification	**MedDRA Preferred Term (v.19.0)**
Eye disorders	Eye pain, Eye irritation

4.9 Overdose

In case of undesirable effects due to an ocular overdose, signs and symptoms may be similar to the local reactions reported with the use of the product (See section 4.8).

Due to the characteristics of this preparation, no toxic effects are to be expected in the event of accidental ingestion of the contents of one bottle/tube.

5. PHARMACOLOGICAL PROPERTIES

OFTALMOLOSA CUSI Antiedema contains 5% sodium chloride which, in contact with the corneal epithelium, acts as a semipermeable membrane that helps to maintain the cornea transparent and devoid of inflammation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E-218)

Propyl parahydroxybenzoate (E-216)

Wool fat

Liquid paraffin
White soft paraffin
Purified water

6.2 Incompatibilities
None

6.3 Nature and contents of storage
Store below 25°C.
Special attention should be given to the expiry date inscription. Once tube has been opened, product should be used during the period of treatment established by physician. Discard any remaining content of product after treatment has been completed (See section 4.2).

This warning is valid for all kinds of eye drops and ophthalmic ointments since, due to their conditions of sterile products; their duration after being opened is very limited.

Discard tube one month after opening.

6.4 Nature and contents of container
5 g tube.

6.5 Instructions for Use and Handling and Disposal
No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

6.6 Manufacturer
See Folding Box.

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