1. NAME OF THE MEDICINAL PRODUCT
®OFTALMOLOSA CUSI Chloramphenicol 1% Eye ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
1 gram of ointment contains 10 mg of chloramphenicol.

3. PHARMACEUTICAL FORM
Eye ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Infections of the anterior pole of the eye (conjunctiva/cornea) caused by germs sensitive to chloramphenicol. In case of severe infections, the ophthalmic application should be completed with the systemic administration of an appropriate antibiotic.

4.2 Posology and method of administration
Dosage
Generally one application in the affected eye every 3 hours, or more frequently during the first 48 hours; the interval between the applications may be increased, but always according to physician's criteria.
Treatment should be continued for at least 48 hours after symptoms have disappeared.

Correct administration procedure
Application to the inside of the eye
Separate the eyelids from the eye and apply an amount of ointment equivalent to a grain of rice into the conjunctival sac.

Application to the outside of the eye
Soften and remove crusts, if any, with warm water, and apply the ointment directly from the tube onto the affected area.
Application of the ointment should be carried out under hygienic conditions, avoiding any contact to the nozzle of the tube.
Close tube after every application.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- Newborn infants
- Patients with history of bone-marrow depression or blood dyscrasias.
- Minor infections, prophylaxis or when less toxic antibacterials could be used.

4.4 Special warnings and precautions for use

- Due to its potential toxic effect on bone marrow, do not use chloramphenicol unless absolutely necessary, and only for infections produced by germs sensitive to the antibiotic (See Section 4.8)
- Excessive blood concentrations may occur after usual doses in patients with hepatic or renal impairment, or in premature and full-term neonates who have immature metabolic processes. This may lead to serious toxic reactions.
- Hypersensitivity reactions including rashes, fever, and angioedema may occur after the use of chloramphenicol containing products. If they occur, discontinue treatment with the product.
- The prolonged use of antibiotics may occasionally result in overgrowth of non-susceptible microorganisms, including fungi. If new infections appear during treatment, or if clinical improvement is not observed within 1 week, therapy should be altered.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant administration of chloramphenicol with other medicines that may cause bone marrow depression should be avoided.

This product should not be used in conjunction with other ophthalmic preparations containing an antibiotic or sulfonamide. Do not use in conjunction with bactericidal antibiotics because of the possibility of antagonism.

4.6 Fertility, pregnancy and lactation

Fertility

There are no data regarding the effects of OFTALMOLOSA CUSI Chloramphenicol eye ointment on male or female fertility.

Pregnancy

There are no or limited amount of data from the use of OFTALMOLOSA CUSI Chloramphenicol eye ointment in pregnant women. Based on human experience, infants can develop a grey syndrome and cardiovascular collapse following systemic exposure to high concentrations of chloramphenicol. Studies

in animals have shown reproductive toxicity. OFTALMOLOSA CUSI Chloramphenicol eye ointment should not be used during pregnancy unless the clinical condition of the woman requires treatment with the product.

Breast-feeding

Systemically administered chloramphenicol is excreted in human milk to such an extent that effects on the breastfed newborns/infants are likely. There is insufficient information on the excretion of chloramphenicol from OFTALMOLOSA CUSI Chloramphenicol eye ointment in human milk. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from OFTALMOLOSA CUSI Chloramphenicol eye ointment therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

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 transient blurred vision occurs upon instillation, the patient must wait until the vision clears before driving or using machinery.

4.8 Undesirable effects

The following adverse reactions have been identified from post-marketing surveillance following administration of CUSI Chloramphenicol eye ointment. Frequency cannot be estimated from the available data.

System Organ Classification	**Adverse reactions** *[MedDRA Preferred Term (16.0)]*
Immune System Disorders	hypersensitivity
Eye disorders	conjunctival oedema, eyelid oedema

Allergic reactions can occur in which event treatment should be interrupted.

Prolonged use of antibiotics may result in overinfections caused by resistant microorganisms. In this case, medication should be discontinued and appropriate therapy initiated.

Description of selected adverse reactions

Chloramphenicol causes two types of bone marrow depression. The most common type is dose-related and usually reversible after discontinuation of the drug. The second form is apparently idiosyncratic, non-dose-related, more serious and generally irreversible bone marrow depression. Although the

majority of cases of blood dyscrasias associated with chloramphenicol have followed the oral use, aplasia has also occurred after intravenous and topical ocular use of the drug. (See Section 4.4)

4.9 Overdose

Due to the characteristics of this preparation, intended for topical use, no toxic effects are expected with the use of this preparation at the recommended dose.
In the event of overdosage or accidental ingestion, consult physician or a Poison Control Center.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chloramphenicol is a broad-spectrum bacteriostatic antibiotic which acts by inhibiting the bacterial protein synthesis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cholesterin
Liquid Paraffin
White soft Paraffin

6.2 Incompatibilities

Not applicable

6.3 Shelf-life

36 months

6.4 Special precautions for storage

Store below 30° C.
Keep all medication out of the reach of children.

6.5 Nature and content of container

3 g tube

6.6 Manufacturer

See folding box
(Information Issued: Apr 2016.SINv1)

Novartis Pharma AG, Basel, Switzerland