SUMMARY OF PRODUCT CHARACTERISTICS

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1. NAME OF THE MEDICINAL PRODUCT

Terricil, 5 mg/g, Eye ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Oxytetracycline hydrochloride at 5 mg/g

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Terricil, 5 mg/g eye ointment is indicated in:
- The treatment of external eye infections due to bacteria (blepharitis, conjunctivitis, keratitis, keratoconjunctivitis, blepharoconjunctivitis, meibomianitis and ocular rosacea).
- The local treatment of trachoma and conjunctivitis caused by Chlamydia.
- Pre and post-operative prophylaxis and, in general, in wounds of the eyeball.

4.2 Posology and method of administration

The posology should be established by the specialist doctor according to each case needs.
Generally, the recommended dose is 2 to 4 times a day, by carefully introducing a little eye ointment into the conjunctival sac (the space between the eye and the eyelid). The eye ointment should be spread by massaging lightly over the eyeball.
Treatment should continue for 48 hours after the symptoms disappearance.
Although there is no systemic absorption of oxytetracycline hydrochloride, the dosage in children and patients with renal or hepatic insufficiency should be determined by the doctor according to the patients' needs.

4.3 Contraindications

Terricil is contraindicated in hypersensitivity to the active substances (oxytetracycline hydrochloride), to tetracyclines and its derivates, or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

When using the eye ointment for the first time, the first portion should be rejected.
Although the treatment of superficial ocular infections is generally empirical, are recommended collections to identify the microorganism, before treatment with Terricil. On rare occasions, as with other antibiotics, the extended use of oxytetracycline may result in opportunistic infections, particularly fungal infections. In such cases, the use of Terricil should be discontinued and the appropriate treatment should be started.
Abnormalities of skeletal and dental development have been reported in children under the age of eight years old following systemic use of tetracyclines. Although such undesirable effects have

never been reported following topical application, the possibility of these events should be considered when oxytetracycline is used in children under the age of eight years old.
There is a possibility of cross hypersensitivity between tetracyclines, whether administered systemically or topically, the existence of any hypersensitivity to tetracyclines should therefore prompt caution in the use of Terricil.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable

4.6 Fertility, pregnancy and lactation

Pregnancy
For this dosage form, there is no evidence of teratogenic effects of oxytetracycline hydrochloride. However, as with all drugs, in pregnant women Terricil should be used only when the possible benefits outweigh the potential risks and under medical surveillance.

4.7 Effects on ability to drive and use machines

Temporary blurred vision may occur, immediately after application, due to the nature of excipients.

4.8 Undesirable effects

In rare occasion, the transient sensation of burning or foreign body on the eyeball may appear, contact allergic eczema, myopia, photophobia and diplopia, reaction that are rare and reversible.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

4.9 Overdose

It is not known for this dosage form.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophtalmologicals. Antiinfectives. Antibiotics.
ATC code: S01AA04

Oxytetracycline hydrochloride is a bacteriostatic aent of large spectrum, that acts through inhibition of protein synthesis, blocking the binding of aminoacyl tRNA to ribossomal complex mRNA. The reversible binding occurs mainly in the 30S ribossomal subunit of susceptible microorganisms. The synthesis of cellular wall is not inhibited.

5.2 Pharmacokinetic properties

Absorption:
The topical use of Oxytetracycline Hydrochloride showed no absorption through ocular mucosa.

Distribution:
Plasmatic protein binding: 27 to 35%. Good intracellular and extracellular diffusion.
Enterohepatic cycle with strong biliary concentration (5 to 6 times the plasmatic levels). Penetrates through the placental barrier. Secretes into breast milk.
Half-life between 8 to 10 hours.

Metabolism:
25% is metabolised to an inactive form.

Elimination:
Renal: 60% of the administered dose is eliminated in 24 hours through glomerular filtration. 75% is eliminated under the inactive form. Renal clearance: 100 ml/min. *Hemodialysis: 60%.

5.3 Preclinical safety data

Oxytetracycline hydrochloride, the active substance of Terricil, is a substance that, from a toxicological perspective, can be used in human, not showing problems that require special measures or are an impediment to its use as therapeutic agent.

Oxytetracycline hydrochloride does not appear to present teratogenic effects.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lanolin anyhdrous and white soft paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Before first opening: 30 months.
After first opening: 28 days.

6.4 Special precautions for storage

Do not store above 25ºC.
Store the tube tightly closed, in the original package, in order to protect from light and moisture.

6.5 Nature and contents of container

Terricil 5 mg/g eye ointment is supplied sterile in a epoxiphenolic lacquered aluminium tube with external white polyester coating and HDPE cap, with capacity for 5 g. previously printed and sterilized by gamma-radiation, containing 5 g of eye ointment. The tubes after filling are packaged in carton boxes, duly printed and accompanied by a package leaflet.

6.6 Special precautions for disposal and other handling

Apply slight pressure on the tube, taking a small amount of ointment, introducing it in the conjunctival sac (the space between the eye and the eyelid). The eye ointment should be spread by massaging lightly over the eyeball.

7. MARKETING AUTHORISATION HOLDER

Laboratório Edol - Produtos Farmacêuticos, S.A.
Avenida 25 de Abril, 6-6A
2795-225 Linda–a–Velha
Portugal

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

11/2014