SUMMARY PRODUCT CHARACTERISTIC (SPC)

TETRACYCLINE EYE OINTMENT 1%

1.1 Trade name – Tetracycline eye ointment 1%

1.2 International non-property name – Tetracycline

2. Qualitative and quantitative composition

Each of 100 gram of Tetracycline eye ointment 1% contains:
active ingredient: Tetracycline-1g
inactive ingredients: see 6.1. List of excipients

3. Pharmaceutical form

Eye ointment
Yellow or yellowish brown ointment.

4. Clinical particulars

4.1 Therapeutic indications

The treatment of bacterial (including chlamydial) eye infections, caused by susceptible to tetracycline microorganisms: blepharitis, blepharoconjunctivitis, keratitis, keratoconjunctivitis, meybomit (sty) and trachoma.

4.2 Posology and method of administration

For topical use.
Squeeze a thin strip (from 0.5 to 1 cm) of ointment for eyelid.
- at blepharitis, blepharoconjunctivitis: 3-4 times per day for 5–7 days;
- at keratitis, keratoconjunctivitis: 2-3 times per day for 5–7 days. If there is no improvement after 3-5 days, it is advisable to consult your doctor.
- at meybomit (sty): at night until signs of inflammation has disappeared.
- at trachoma: every 2-4 hours or more frequently for 1to 2 weeks. After subsidence of inflamation the drug can be used 2-3 times per day. Duration of therapy: 1-2 months.

4.3 Contraindications

- Hypersensitivity to any compounds of drug;
- kidney and liver disorders;
- pregnancy;
- breastfeeding;
- children under 8 years.

4.4 Special warnings and precautions for use

After applying the ointment can be blurred vision, so it is not recommended to drive vehicles or engage in activities that require visual acuity prior to its recovery.

4.5 Interaction with other medicinal products and other forms of interaction

Drug interactions are not described.

4.6. Pregnancy and lactation
Tetracycline eye ointment 1% is contraindicated during pregnancy and lactation.

4.7 Effects on ability to drive and use machines
After applying the ointment can be blurred vision, so it is not recommended to drive vehicles or engage in activities that require visual acuity prior to its recovery.

4.8 Undesirable effects
Allergic reactions, palpebral oedema and hyperemia, transient blurry vision.

4.9 Overdose
Data for overdosage are not available.

5. Pharmacological properties
5.1 Pharmacodynamic properties
Antibiotics.Tetracycline. S01AA09
Bacteriostatic antibiotic from the tetracycline group. Tetracyclines inhibit protein synthesis by impairing the stable binding of aminoacyl-transfer (t)RNA to the bacterial ribosomal A-site. It is active against gram-positive and gram-negative microorganisms: Staphylococcus aureus, Streptococcus pyogenes, Streptococcus pneumoniae, Neisseria gonorrhoeae, Haemophilus influenzae, Haemophilus ducreyi, Klebsiella pneumoniae, Francisella tularensis, Escherichia coli, Bacillus anthracis, Chlamydia trachomatis. Tetracycline is not active against Haemophilus influenzae, Klebsiella spp., Aerobacter spp., Pseudomonas aeruginosa, Serratia marcescens.

5.2 Pharmacokinetic properties
After topical application therapeutic concentration of tetracycline is achieved in the ocular tissue, systemic absorption is low.
At the corneal epithelial damage effective concentration of tetracycline achieved in 30 minutes after application in liquid of anterior chamber of the eye.

6. Pharmaceutical particulars
6.1 List of excipients
Lanolin anhydrous – 40g,
Petrolatum ophtalmic –to 100g.

6.2 Incompatibilities
None stated.

6.3 Shelf life
3 years. Do not use this medicine after the expiry date.

6.4 Special precautions for storage
Store in a dry place at temperature not higher than 15°C, out of the reach of children. Protect from light.

6.5 Nature and contents of container
3 g of eye ointment in aluminum tubes with bouchons for medical ointments. A tube with leaflet inserted in the cardboard box.

6.6 Special precautions for disposal and other handling

Not applicable

7. MANUFACTURER AND MARKETING AUTHORISATION HOLDER

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