SUMMARY PRODUCT CHARACTERISTIC (SPC)

TETRACYCLINE EYE OINTMENT 1%

1. Name of the medicinal product – TETRACYCLINE EYE OINTMENT 1%

2. Qualitative and quantitative composition
Each of 100 gram of TETRACYCLINE EYE OINTMENT 1% contains:
active ingredient: Tetracycline – 1 g
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
If the patient's response to the drug has not improved within a few days, the physician should be consulted regarding further use of the drug.
Concomitant use of ophthalmic tetracycline and topical corticosteroids (dexamethasone, prednisolone, hydrocortisone) should be avoided because of the potential for masking

clinical signs of bacterial, viral, or fungal infections. Corticosteroids may inhibit hypersensitivity reactions to tetracycline.
As with other antibacterial drugs, tetracycline may result in overgrowth of non-susceptible strains of bacteria or fungi with prolonged repeated use or concomitant use with other antibacterial drugs. If superinfection occurs, it is recommended to stop using the drug and initiate appropriate treatment.
Due to the possible development of photodermatoses (increased photosensitivity when using tetracycline antibiotics), the drug should not be used when exposed to sunlight or UV radiation.
Tetracycline should be discontinued at the first appearance of skin rash or other signs of hypersensitivity.
Patients should not wear contact lenses if they have an eye infection.
Since the medicinal product contains lanolin as an excipient, it may cause local skin reactions (e.g. contact dermatitis).

4.5. Interaction with other medicinal products and other forms of interaction
When using tetracycline locally for ophthalmologic purposes, it should be borne in mind that its bacteriostatic action may interfere with the bactericidal action of penicillins, cephalosporins and aminoglycosides. Their simultaneous use, both locally and systemically, should be avoided.
The use of tetracycline in patients using contact lens solution containing 0.004% thiomersal has been associated with varying degrees of ocular reactions (eye redness, irritation, blepharitis). Eye inflammation has occurred in some patients using tetracycline concomitantly with ophthalmic preparations containing thiomersal. Concomitant use of tetracycline with medications and/or contact lens solutions containing thiomersal should be avoided.
Concomitant ophthalmic use of tetracycline and topical corticosteroids should be avoided (see section "Special warnings and precautions for use").
To increase effectiveness, combined use with erythromycin, oleandomycin, and nitrofuran drugs is possible.
It should not use cosmetics containing retinoids while using tetracycline.

4.6. Pregnancy and lactation
The efficacy and safety of the drug during pregnancy or breastfeeding have not been sufficiently studied, so the drug should not be used in this category of patients.

4.7. Effects on ability to drive and use machines
As with all ophthalmic agents, temporary blurred vision or other visual disturbances are possible, which may affect the ability to drive a vehicle or operate other machinery.
Until vision clarity is restored, patients should refrain from driving vehicles and operating with other mechanisms.

4.8. Undesirable effects

Eye disorders: blurred vision, acute pain, itching of the eyes or eyelids, conjunctival hyperemia, irritation of the mucous membrane of the eyelids, eyelid edema, increased lacrimation and pain in the eyes. Myopia in patients using tetracyclines may be caused by temporary hydration of the lens.

Immune system disorders: local allergic reactions - dermatitis, rash, itching, burning, inflammation, photodermatitis (increased sensitivity to sunlight and UV radiation); generalized allergic reactions, in particular rash, fixed drug rash, exfoliative dermatitis, Quincke's edema, itching and swelling of the face, tongue, throat, dizziness, shortness of breath. In such cases, use of the ointment should be discontinued.

Gastrointestinal disorders: loss of appetite, nausea, vomiting, diarrhea, possible inflammatory processes in the tongue, stomatitis, gastritis, proctitis.

Infections and infestations: Candidiasis (growth of Candida albicans), overgrowth of persistent coliform organisms (Pseudomonas, Proteus) may occur.

General disorders: Cases of increased muscle weakness in patients with myasthenia gravis and exacerbation of lupus erythematosus have been reported with long-term use of tetracycline.

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 online to the Center of Drug and Medical Technologies Expertise of MoH of RA via www.pharm.am or call the hotline numbers: (+374 0) 20 05 05 and (+374 96) 22 05 05.

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 – 40 g,
Petrolatum ophtalmic – to 100 g.

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. Marketing authorization holder

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