Terramycin®

Oxytetracycline HCl eq. to Oxytetracycline 5mg + Polymyxin B Sulphate eq. to Polymyxin B 10.000 IU

Ophthalmic Ointment

5 mg/g + 10000 UI/g

Reference market: Belgium

AfME markets using this LPD: Egypt

SUMMARY OF PRODUCT CHARACTERISTICS

Egypt, March 2024

1. NAME OF THE MEDICINAL PRODUCT

Terramycin®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Terramycin® 5 mg /g + 10000 UI/g contains in 1 gram of eye ointment:
- 5 mg of oxytetracycline (present as oxytetracycline hydrochloride(micronized) 5.396 mg)
- 10,000 I.U. of polymyxin B (present as polymyxin B sulphate(micronized) 1.6667 mg)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye ointment.

Light yellow homogenous smooth ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Terramycin® 5 mg /g + 10000 UI/g eye ointment is indicated in the treatment of superficial ocular infections involving the conjunctiva and/or cornea due to susceptible microorganisms.

Topical application of Terramycin® 5 mg /g + 10000 UI/g eye ointment should be supplemented with systemic antibiotic administration when infection is deep seated.

4.2 Posology and method of administration

Posology
Terramycine (with polymyxin B sulphate) eye ointment should be applied in a small quantity (approximately 1 cm) into the conjunctival sac of the lower lid 4 to 6 times daily until the infection is cleared and healing is complete. Treatment may take from one day to several weeks depending on the nature and severity of the infection.

In blepharitis, scales and crusts should be removed before applying medication. For prophylaxis in surgery, the same procedure is followed on the day before operation and subsequently for several days following it.

The patient should be instructed to avoid contamination of the tip of the tube when topically applying the eye ointment.

Method of administration
Ophthalmic route.
External use.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

As with other antibiotics, Terramycine eye ointment may result in overgrowth of other non-susceptible microorganisms including fungi. Constant observation of the patient is essential. If new infections due to non-susceptible microorganisms or fungi appear during therapy, appropriate therapy should be instituted as indicated by susceptibility testing.
In case of severe infection or if a favourable response to topical treatment does not occur, ophthalmic application of oxytetracycline and polymyxin B should be supplemented with a systemic therapy.

This medicinal product was treated with ionizing radiations.

Paediatric population:
Systemic administration of tetracyclines during tooth development (last half of pregnancy, infancy, and childhood to the age of 8 years) may cause permanent discoloration of the teeth as well as retardation in the development of the skeleton. Enamel hypoplasia has also been reported. Although these effects are unlikely following topical application of tetracyclines because of the low doses used, the possibility that these effects could occur should be considered.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction has been established to date.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no controlled studies to date using topical tetracyclines in pregnant women. The use of systemic tetracyclines in pregnant women has resulted in retardation of skeletal development and bone growth in the foetus.
A possible association between oral administration of tetracyclines during pregnancy and cases of isolated cleft lips with or without cleft palate has been established in population-based case-control studies.
Medicinal products of this class should be used during pregnancy only when the possible benefits outweigh the potential risks.

Breastfeeding
It is not known whether topical tetracyclines are excreted in breast milk. Tetracyclines are distributed into milk following systemic administration. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or discontinue the medicinal product, taking into account the importance of the medicinal product to the mother.

Fertility
There are no human data on the effects of oxytetracycline or polymyxin B on fertility. Animal studies did not identify adverse effects on fertility (see section 5.3). The potential risk for humans is unknown.

4.7 Effects on ability to drive and use machines

Use of eye ointment may temporarily impair vision.

4.8 Undesirable effects

System organ class	Very common ≥1/10	Common ≥1/100 to <1/10	Uncommon ≥1/1,000 to <1/100	Rare ≥1/10,000 to <1/1,000	Very rare <1/10,000	Frequency not known (cannot be estimated from the available data)

Immune system disorders						Hypersensitivity*
Eye disorders						Eye pain, eye irritation, sensation of the presence of a foreign body in the eye, increased lacrimation
Skin and subcutaneous tissue disorders						Contact dermatitis*
* If such reactions occur, therapy should be discontinued.						

4.9 Overdose

No overdosage has been reported during use of oxytetracycline eye ointment
There is no specific antidote available. In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Combination of antibiotics for ophthalmic use
ATC code: S01A A30

Mechanism of action:
Oxytetracycline is a product of the metabolism of *Streptomyces rimosus* and belongs to the family of tetracycline antibiotics. The 1 % oxytetracycline solution in water is acidic (pH about 2.5). Its activity is affected in solutions less acidic than pH 2 and it is rapidly destroyed by alkaline hydroxides.

Pharmacodynamic effects:
Oxytetracycline is primarily bacteriostatic and is thought to exert its antimicrobial effect by the inhibition of protein synthesis. Oxytetracycline is active against a wide range of Gram-negative and Gram-positive microorganisms, such as staphylococci, streptococci, pneumococci, *Haemophilus influenzae* and the Koch-Weeks bacillus, gonococci, and *Chlamydia trachomatis*, which is often seen in eye infections. Antibiotics in the tetracycline class have closely similar antimicrobial spectra, and cross-resistance among them is common.

Polymyxin B sulphate belongs to a group of related antibiotics derived from *Bacillus polymyxa*. It is rapidly bactericidal, this action being exclusively against Gram-negative microorganisms. Polymyxin B sulphate is particularly effective against *Pseudomonas aeruginosa* and *Haemophilus aegyptius*, frequently found in local infections of the eye.

One mg of pure polymyxin B is equivalent to 10,000 units.

The association of the broad-spectrum antibiotic oxytetracycline and polymyxin B is an effective antibiotic combination against primary or secondary infectious pathogens.

5.2 Pharmacokinetic properties

Absorption

Data on topical absorption of these antibiotics when used to treat ophthalmic conditions are not available.

5.3 Preclinical safety data

Oxytetracycline
Oxytetracycline was well-tolerated with an absence of significant toxicological findings following single or repeated administration at high doses. The only toxicological hazards identified were limited to liver and kidney at doses expected to greatly exceed exposure from topical uses. Oxytetracycline is not genotoxic or tumorigenic. Oxytetracycline administered to pregnant dogs at high doses resulted in resorptions, skeletal and visceral malformations.

Polymyxin B sulphate
High doses of Polymyxin B sulfate targets the kidney in rodents and dogs. Administration in the eye by intravitreal injection results in opacity of the lens, administration in the ear results in toxicity of the middle ear.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Heavy mineral oil - White petrolatum

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Do not use Terramycin after the expiry date which is stated on the carton after EXP:. The expiry date refers to the last day of that month.

6.4 Special precautions for storage

For Storage condititions: Look at the outer pack.

Terramycine eye ointment (with polymyxin B sulphate) will retain its effect until the date shown on the packaging (date: month-year).

6.5 Nature and contents of container

Carton box containing 100 collapsible aluminum tubes tip covered with aluminum layer and HDPE plastic cap, each of 5 gm ointment and inner leaflet

6.6 Special precautions for disposal

Keep out of the sight and reach of children.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. FURTHER INFORMATION

MARKETING AUTHORIZATION HOLDER :
Pfizer Inc., USA

MANUFACTURER & PACKAGER :
Viatris Egypt

8. DATE OF REVISION OF THE TEXT

January 2017

TO REPORT SIDE EFFECT(S):

Pharmacovigilance center, Pfizer Pharmaceutical Company: EGY.AEReporting@pfizer.com
Egyptian Pharmacovigilance center (EPVC), EDA: pv.followup@edaegypt.gov.eg

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the Pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach and sight of children

Council of Arab Health Ministers

Union of Arabic Pharmacists