

SUMMARY OF PRODUCT CHARACTERISTICS
(SmPC)

Thromycin[®] Eye Ointment
(Erythromycin 0.5%)

1. NAME OF THE MEDICINAL PRODUCT

Thromycin[®] Eye Ointment (Erythromycin 0.5%)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Tube contains Erythromycin 0.5%.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment

4. Clinical particulars

4.1 Therapeutic indications

Erythromycin eye ointment is indicated for the treatment of superficial ocular infections involving the conjunctiva and or cornea caused by organisms susceptible to Erythromycin. For prophylaxis of ophthalmia neonatorum (this is a type of pink eye that caused blindness in 3% of infants who were affected) due to *N. gonorrhoeae* or *C. trachomatis*. The effectiveness of Erythromycin is the prevention of ophthalmia caused by penicillinase- producing *N. gonorrhoeae* is not established.

4.2 Posology and method of administration

In the treatment of superficial ocular infections, a ribbon approximately 1 cm in length of Erythromycin Ophthalmic Ointment should be applied directly to the infected structure up to 6 times daily, depending on the severity of the infection.
For prophylaxis of neonatal gonococcal or chlamydial conjunctivitis, a ribbon of ointment approximately 1 cm in length should be instilled into each lower conjunctival sac. The ointment should not be flushed from the eye following instillation. A new tube should be used for each infant.

4.3 Contraindications

This drug is contraindicated in patients with a history of hypersensitivity to erythromycin.

4.4 Special warnings and precautions for use

May result in overgrowth of nonsusceptible organisms including fungi; in such a case, antibiotic administration should be stopped and appropriate measures taken.

Avoid contaminating the applicator tip with material from the eye, fingers, or other source.

4.5 Interaction with other medicinal products and other forms of interaction

Do not use this medication wearing contact lenses, wait at least 15 minutes after using Erythromycin eye ointment before putting your contact lenses on.

Do not use other eye medications during treatment with erythromycin eye ointment unless prescribed by a doctor. It is not likely that oral drugs or intravenous will have an effect on erythromycin ophthalmic used in the eyes.

4.6 Pregnancy and Lactation

Pregnancy category B

Reproduction studies have been performed in rats, mice and rabbits using Erythromycin and its

various salt and esters, at doses that were several multiples of usual human doses. There are however no adequate and well controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, the Erythromycin should be used during pregnancy only if clearly needed.

Lactation

It is not known whether erythromycin eye ointment passes into the breast milk or if it could harm a nursing baby.

4.7 Effects on ability to drive and use machines

No or negligible influence.

Undesirable effects The most frequently reported adverse reactions are minor ocular irritations redness, hypersensitivity reactions, burning and stinging, increased sensitivity to lights.

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 to the appropriate authorities.

4.8 Overdose

Thromycin[®] is for ophthalmic use only, if the product is used excessively no more rapid or better results will be obtained, marked redness or discomfort could occur. If these effects should occur, the frequency of application could be reduced or treatment discontinued and appropriate symptomatic therapy instituted.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Erythromycin is a macrolide antibiotic active in vivo and in vitro against most aerobic and anaerobic gram-positive bacteria as well as some gram-negative bacilli.

Erythromycin is usually bacteriostatic in action but may be bactericidal in high concentration or against highly susceptible organism. Erythromycin appears to inhibit protein synthesis in susceptible organism by reversibly binding to 50 s ribosomal subunits. The sterile ophthalmic ointments flows freely over the conjunctiva.

Microbiology: Erythromycin inhibits protein synthesis without affecting nucleic acid synthesis. Erythromycin is usually active against the following organisms in vitro and in clinical infections:

Streptococcus pyogenes (group A β -hemolytic)

Alpha-hemolytic streptococci (viridans group)

Staphylococcus aureus, including penicillinase-producing strains (methicillin-resistant staphylococci are uniformly resistant to erythromycin)

Streptococcus pneumoniae

Mycoplasma pneumoniae (Eaton Agent, PPLO)

Haemophilus influenzae (not all strains of this organism are susceptible at the erythromycin concentrations ordinarily achieved)

Treponema pallidum

Corynebacterium diphtheriae

Neisseria gonorrhoeae

Chlamydia trachomati

5.2 Pharmacokinetic properties

It is unknown whether erythromycin is absorbed from mucus membrane to any substantial extent.

5.3 Preclinical safety data

There is no relevant information additional to that contained elsewhere in the Summary of Product Characteristics.

6.0 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin (light)

White Soft Paraffin

Incompatibilities

6.2 Shelf life

48 months

6.3 Special precautions for storage

Store below 30°C

protect from light and moisture.

6.4 Nature and contents of container and special equipment for use, administration or implantation

Thromycin[®] Eye Ointment is presented in a tube with total content of 3.5g in a hardboard carton with leaflet enclosed.

6.5 Special precautions for disposal and other handling

Not applicable.

7.0 APPLICANT/MANUFACTURER

Drugfield Pharmaceuticals Limited
Lynson Chemical Avenue Km38,
Lagos-Abeokuta Expressway
Sango-Otta, Ogun State, Nigeria
Tel: +2348033513989
Email:Info@drugfieldpharma.com