DESCRIPTION: ILOTYCIN® (erythromycin) Ophthalmic Ointment USP 0.5% (5 mg/g) is a sterile ophthalmic base of mineral oil and white petrolatum. Each gram contains Erythromycin USP 5 mg in a sterile ophthalmic base of mineral oil and white petrolatum.

CLINICAL PHARMACOLOGY: 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 ß-hemolytic)
- Alpha-hemolytic streptococci (viridans group)
- Staphylococcus aureus, including penicillinase-producing strains (methicillin-resistant staphylococci)
- Haemophilus influenzae
- Neisseria gonorrhoeae
- Chlamydia trachomatis

INDICATIONS AND USAGE: For the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by organisms susceptible to erythromycin.

- For prophylaxis of ophthalmia neonatorum due to gonococcal or chlamydial conjunctivitis, a ribbon of ointment approximately 1 cm in length of ILOTYCIN® Ophthalmic Ointment USP should be applied to the infected structure up to 6 times daily, depending on the severity of the infection. A new tube should be used for each infant. For prophylaxis of neonatal gonococcal or chlamydial conjunctivitis, a ribbon of ointment approximately 1 cm in length of ILOTYCIN® Ophthalmic Ointment USP 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.

HOW SUPPLIED: Sterile ILOTYCIN® Ophthalmic Ointment USP, 5 mg/g as follows:

- 0.5% (5 mg/g) as follows:

- 0.5% (5 mg/g)

- STERILE

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

PRECAUTIONS: General: The use of antimicrobial agents may be associated with the overgrowth of nonsusceptible organisms including fungi; in such a case, antibiotic administration should be stopped and appropriate measures taken.

Information for Patients: Avoid contaminating the applicator tip with material from the eye, fingers, or other source.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Two year oral studies conducted in rats with erythromycin did not provide evidence of tumorigenicity. Mutagenicity studies have not been conducted. No evidence of impaired fertility that appeared related to erythromycin was reported in animal studies.

Pregnancy: Teratogenic effects — Pregnancy category B: Reproduction studies have been performed in rats, mice, and rabbits using erythromycin and its various salts and esters, at doses that were several multiples of the usual human dose. No evidence of harm to the fetus that appeared related to erythromycin was reported in these studies. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, the erythromycins should be used during pregnancy only if clearly needed.

Pediatric Use: Caution should be exercised when erythromycin is administered to a nursing woman. Nursing Mothers: Caution should be exercised when erythromycin is administered to a nursing woman.

ADVERSE REACTIONS: The most frequently reported adverse reactions are minor ocular irritations, redness, and hypersensitivity reactions.

Pediatric Use: See INDICATIONS AND USAGE and DOSAGE AND ADMINISTRATION.

Stability: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Avoid excessive heat. Protect from freezing.

Preventive Medicine

Ophthalmic Ointment USP 0.5% (5 mg/g)

Rx Only

Ophthalmic Ointment USP 0.5% (5 mg/g)
DESCRIPTION: ILOTYCIN® (erythromycin) Ophthalmic Ointment belongs to the macrolide group of antibiotics. It is basic and readily forms a salt when combined with an acid. The base, as crystals or powder, is slightly soluble in water, moderately soluble in ether, and readily soluble in alcohol or chloroform. Erythromycin (I3P, 4S, 5S, 6R, 7R, 8R, 11R, 12R, 13S, 14R)-4-[2,6-dideoxy-3-C-methyl-3-0-methyl-a-D-ribo-hexopyranosyloxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[2,4,6-trideoxy-3-(dimethylamino)-2-0-spirohexopyranosyloxy]oxyxacyclotetradecane-2,10-dione is an antibiotic produced from a strain of Streptomyces erythraeus. It has the following structural formula:

Molecular Formula: C37H67NO13
Molecular Weight: 733.94

Each gram contains Erythromycin USP 5 mg in a sterile ophthalmic base of mineral oil and white petrolatum.

CLINICAL PHARMACOLOGY: 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 beta-hemolytic)
- Alpha-hemolytic streptococci (various 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 to erythromycin concentrations ordinarily achieved)
- Trepomonas pallidum
- Corynebacterium diphtheriae
- Neisseria gonorrhoeae
- Chlamydia trachomatis

INDICATIONS AND USAGE: For the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by organisms susceptible to erythromycin.

For prophylaxis of ophthalmia neonatorum due to N. gonorrhoeae or C. trachomatis.

The effectiveness of erythromycin in the prevention of ophthalmia caused by penicillinase-producing N. gonorrhoeae is not established.

For infants born to mothers with clinically apparent gonorrhea, intravenous or intramuscular injections of N. gonorrhoeae should be given; a single dose of 50,000 units for term infants or 20,000 units for infants of low birth weight. Topical prophylaxis alone is inadequate for these infants.

For infants born to mothers with clinically apparent gonorrhea, intravenous or intramuscular injections of N. gonorrhoeae should be given; a single dose of 50,000 units for term infants or 20,000 units for infants of low birth weight. Topical prophylaxis alone is inadequate for these infants.

For prophylaxis of ophthalmia neonatorum due to N. gonorrhoeae and/or cornea caused by organisms susceptible to erythromycin.

DOSAGE AND ADMINISTRATION:

Pediatric Use:

Nursing Mothers:
The use of antimicrobial agents may be associated with the overgrowth of nonsusceptible organisms including fungi; in such a case, antibiotic administration should be stopped and appropriate measures taken.

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

PRECAUTIONS: General: The use of antimicrobial agents may be associated with the overgrowth of nonsusceptible organisms including fungi; in such a case, antibiotic administration should be stopped and appropriate measures taken.

Information for Patients: Avoid contaminating the applicator tip with material from the eye, fingers, or other source.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Two year oral studies conducted in rats with erythromycin did not provide evidence of tumorigenicity. Mutagenicity studies have not been conducted. No evidence of impaired fertility that appeared related to erythromycin was reported in these studies. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, the erythromycins should be used during pregnancy only if clearly needed.

Nursing Mothers: Caution should be exercised when erythromycin is administered to a nursing woman.

Pediatric Use: See INDICATIONS AND USAGE and DOSAGE AND ADMINISTRATION.

ADVERSE REACTIONS: The most frequently reported adverse reactions are minor ocular irritations, redness, and hypersensitivity reactions.

To report SUSPECTED ADVERSE REACTIONS, contact Perrigo at 1-866-634-9120 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSE AND ADMINISTRATION: In the treatment of superficial ocular infections, a ribbon 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.

HOW SUPPLIED: Sterile ILOTYCIN® Ophthalmic Ointment USP, 5 mg/g as follows:

1 g tamper-evident tubes
NDC 0574-4023-11

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Avoid excessive heat. Protect from freezing.

MANUFACTURED FOR:
Perrigo®
Minneapolis, MN 55427
10000 RC J1 Nov 08-13 A
R0813
SH 0813

Scale = 100%