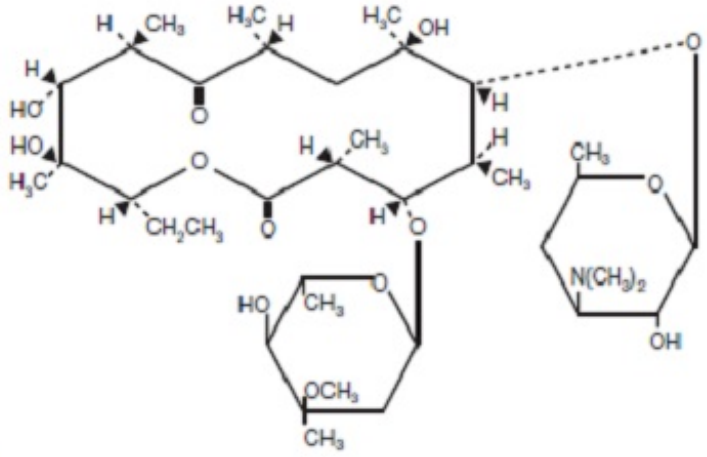
ERYTHROMYCIN- erythromycin ointment
Padagis US LLC

ERYTHROMYCIN OPHTHALMIC OINTMENT USP
STERILE
RX ONLY

DESCRIPTION:

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 ((3R*,4S*,5S*,6R*,7R*,9R*,11R*,12R*,13S*,14R*)-4-[(2,6-dideoxy-3-*C*-methyl-3-*0*-methyl-α-L-*ribo*-hexopyranosyl)oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethylamino)-ß-D-*xylo*-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione) is antibiotic produced from a strain of *Streptomyces erythraeus*. It has the following structural formula:



Molecular Formula: $C_{37}H_{67}NO_{13}$
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 ß-hemolytic)

Alpha-hemolytic streptococci (viridans group)

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

Streptococcus pneumonia

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 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. gonorrheae* is not established.

For infants born to mothers with clinically apparent gonorrhea, intravenous or intramuscular injections of aqueous crystalline penicillin G 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.

CONTRAINDICATIONS:

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.

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 Padagis® at 1-866-634-9120 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND 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.

HOW SUPPLIED

Sterile Erythromycin Ophthalmic Ointment USP, 5 mg/g as follows:

3.5 g (1/8 oz) tamper-evident tubes NDC 0574-**4024**-35

24 x 3.5 g (1/8 oz) Hospital-Pak (for hospital use only) NDC 0574-**4024**-39

Carton of fifty (50) Unit Dose 1 g tubes NDC 0574-**4024**-50

Store at controlled room temperature 15°-30°C (59°-86°F). Avoid excessive heat.

Protect from freezing.

Manufactured for Padagis®
Minneapolis, MN 55427

www.padagis.com

Rev 02-23
5W700 RC PH

Package/Label Display Panel - Label

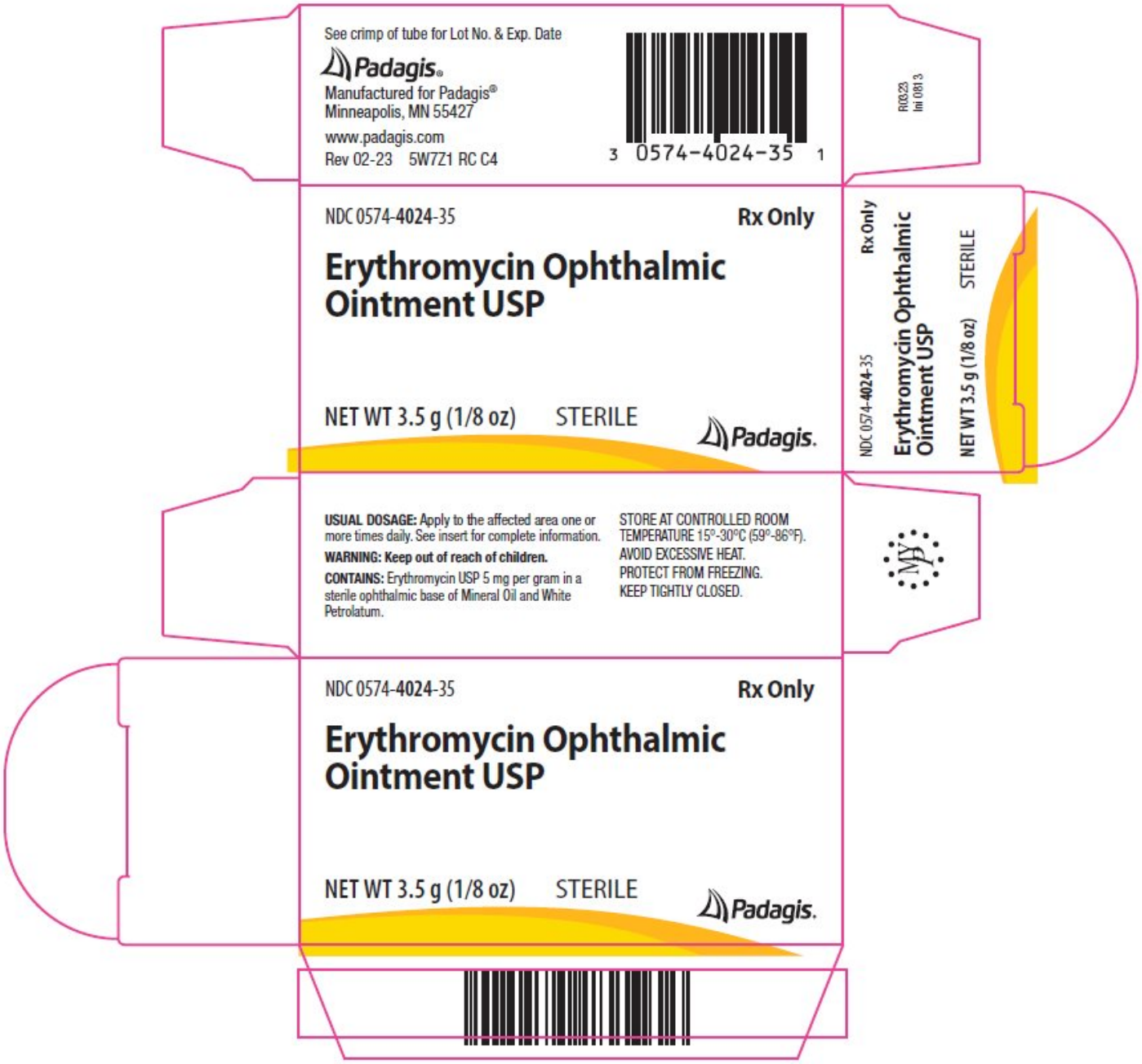
NDC 0574-4024-35

Rx Only

Erythromycin Ophthalmic Ointment USP

NET WT 3.5 g (1/8 OZ)

STERILE



The following image is a placeholder representing the product identifier that is either affixed or imprinted on the drug package label during the packaging operation.

S/N [insert product's serial number]
Lot [insert product's lot number]
Exp [insert product's expiration date]

ERYTHROMYCIN

erythromycin ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0574-4024
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ERYTHROMYCIN (UNII: 63937KV33D) (ERYTHROMYCIN - UNII:63937KV33D)	ERYTHROMYCIN	5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0574-4024-35	1 in 1 CARTON	05/08/2014	
1		3.5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0574-4024-39	24 in 1 CARTON	05/08/2014	
2		3.5 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0574-4024-50	50 in 1 CARTON	05/08/2014	
3		1 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062447	05/08/2014	

Labeler - Padagis US LLC (967694121)

Revised: 11/2024 Padagis US LLC