

ERYTHROMYCIN AND BENZOYL PEROXIDE- erythromycin and benzoyl peroxide gel

Rising Pharma Holdings, Inc.

Erythromycin and Benzoyl Peroxide Topical Gel USP

TO THE PHARMACIST: IMPORTANT: PLEASE READ COMPLETE COMPOUNDING DIRECTIONS

NOTE: PRIOR TO DISPENSING, TAP VIAL UNTIL ALL POWDER FLOWS FREELY. ADD INDICATED AMOUNT OF ROOM TEMPERATURE 70% ETHYL ALCOHOL TO VIAL (TO THE MARK) AND IMMEDIATELY SHAKE **VIGOROUSLY** TO **COMPLETELY** DISSOLVE ERYTHROMYCIN, THEN **IMMEDIATELY** ADD THIS SOLUTION TO GEL AND STIR UNTIL HOMOGENEOUS IN APPEARANCE (1 TO 1-1/2 MINUTES).

Erythromycin and Benzoyl Peroxide Topical Gel USP

Topical Gel: erythromycin (3%),
benzoyl peroxide (5%)

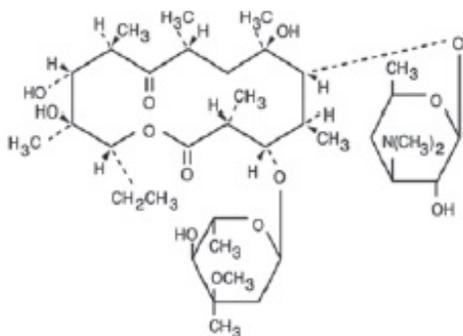
For Dermatological Use Only – Not for Ophthalmic Use

Reconstitute Before Dispensing

DESCRIPTION

Erythromycin and Benzoyl Peroxide Topical Gel USP contains erythromycin [(3R*, 4S*, 5S*, 6R*, 7R*, 9R*, 11R*, 12R*, 13S*, 14R*)-4-[(2,6-Dideoxy-3-C-methyl-3-O-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)- β -D-xylo-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione]. Erythromycin is a macrolide antibiotic produced from a strain of *Saccharopolyspora erythraea* (formerly *Streptomyces erythreus*). It is a base and readily forms salts with acids.

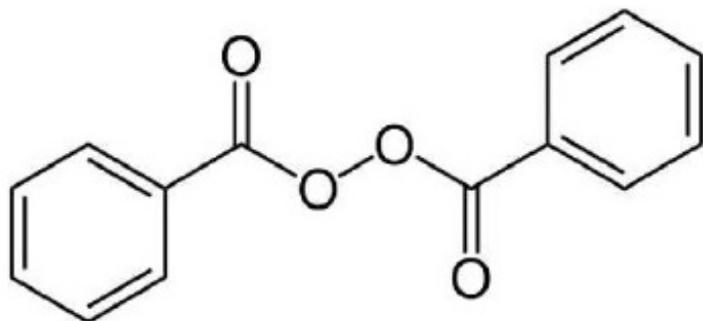
Chemically, erythromycin is (C₃₇H₆₇NO₁₃). It has the following structural formula:



Erythromycin has the molecular weight of 733.94. It is a white crystalline powder and has a solubility of approximately 1 mg/mL in water and is soluble in alcohol at 25°C.

Erythromycin and Benzoyl Peroxide Topical Gel USP also contains benzoyl peroxide for topical use. Benzoyl peroxide is an antibacterial and keratolytic agent.

Chemically, benzoyl peroxide is (C₁₄H₁₀O₄). It has the following structural formula:



Benzoyl peroxide has the molecular weight of 242.23. It is a white granular powder and is sparingly soluble in water and alcohol and soluble in acetone, chloroform and ether.

Each gram of Erythromycin and Benzoyl Peroxide Topical Gel USP contains, as dispensed, 30 mg (3%) of erythromycin and 50 mg (5%) of benzoyl peroxide in a base of purified water USP, carbomer 940 NF, ethyl alcohol 20%, sodium hydroxide NF, docusate sodium and fragrance.

CLINICAL PHARMACOLOGY

The exact mechanism by which erythromycin reduces lesions of acne vulgaris is not fully known; however, the effect appears to be due in part to the antibacterial activity of the drug.

Benzoyl peroxide has a keratolytic and desquamative effect which may also contribute to its efficacy. Benzoyl peroxide has been shown to be absorbed by the skin where it is converted to benzoic acid.

Microbiology

Erythromycin acts by inhibition of protein synthesis in susceptible organisms by reversibly binding to 50 S ribosomal subunits, thereby inhibiting translocation of aminoacyl transfer-RNA and inhibiting polypeptide synthesis. Antagonism has been demonstrated *in vitro* between erythromycin, lincomycin, chloramphenicol and clindamycin.

Benzoyl peroxide is an antibacterial agent which has been shown to be effective against *Propionibacterium acnes*, an anaerobe found in sebaceous follicles and comedones. The antibacterial action of benzoyl peroxide is believed to be due to the release of active oxygen.

INDICATIONS AND USAGE

Erythromycin and Benzoyl Peroxide Topical Gel USP is indicated for the topical treatment of acne vulgaris.

CONTRAINDICATIONS

Erythromycin and Benzoyl Peroxide Topical Gel USP is contraindicated in those

individuals who have shown hypersensitivity to any of its components.

WARNINGS

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including erythromycin, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of "antibiotic-associated colitis."

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation and treatment with an antibacterial drug clinically effective against *C. difficile* colitis.

PRECAUTIONS

General: For topical use only; not for ophthalmic use. Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating or abrasive agents. If severe irritation develops, discontinue use and institute appropriate therapy.

The use of antibiotic agents may be associated with the overgrowth of nonsusceptible organisms including fungi. If this occurs, discontinue use and take appropriate measures.

Avoid contact with eyes and all mucous membranes.

Information for Patients: Patients using Erythromycin and Benzoyl Peroxide Topical Gel USP should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes, nose, mouth, and all mucous membranes.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. Patients should not use any other topical acne preparation unless otherwise directed by physician.
4. Patients should report to their physician any signs of local adverse reactions.
5. Erythromycin and Benzoyl Peroxide Topical Gel USP may bleach hair or colored fabric.
6. Keep product refrigerated and discard after 3 months.

Carcinogenesis, Mutagenesis and Impairment of Fertility: Data from a study using mice known to be highly susceptible to cancer suggests that benzoyl peroxide acts as a tumor promoter. The clinical significance of this is unknown.

No animal studies have been performed to evaluate the carcinogenic and mutagenic potential or effects on fertility of topical erythromycin. However, long-term (2-year) oral

studies in rats with erythromycin ethylsuccinate and erythromycin base did not provide evidence of tumorigenicity. There was no apparent effect on male or female fertility in rats fed erythromycin (base) at levels up to 0.25% of diet.

Pregnancy: Teratogenic Effects:

Animal reproduction studies have not been conducted with Erythromycin and Benzoyl Peroxide Topical Gel USP or benzoyl peroxide.

There was no evidence of teratogenicity or any other adverse effect on reproduction in female rats fed erythromycin base (up to 0.25% diet) prior to and during mating, during gestation and through weaning of two successive litters.

There are no well-controlled trials in pregnant women with Erythromycin and Benzoyl Peroxide Topical Gel USP. It also is not known whether Erythromycin and Benzoyl Peroxide Topical Gel USP can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Erythromycin and Benzoyl Peroxide Topical Gel USP should be given to a pregnant woman only if clearly needed.

Nursing Women: It is not known whether Erythromycin and Benzoyl Peroxide Topical Gel USP is excreted in human milk after topical application. However, erythromycin is excreted in human milk following oral and parenteral erythromycin administration. Therefore, caution should be exercised when erythromycin is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of this product in pediatric patients below the age of 12 have not been established.

ADVERSE REACTIONS

In controlled clinical trials, the incidence of adverse reactions associated with the use of Erythromycin and Benzoyl Peroxide Topical Gel USP was approximately 3%. These were dryness and urticarial reaction.

The following additional local adverse reactions have been reported occasionally: irritation of the skin including peeling, itching, burning sensation, erythema, inflammation of the face, eyes and nose, and irritation of the eyes. Skin discoloration, oiliness and tenderness of the skin have also been reported.

To report SUSPECTED ADVERSE REACTIONS, contact Rising Pharma Holdings, Inc. at 1-844-874-7464 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

Erythromycin and Benzoyl Peroxide Topical Gel USP should be applied twice daily, morning and evening, or as directed by a physician, to affected areas after the skin is thoroughly washed, rinsed with warm water and gently patted dry.

How Supplied and Compounding Directions

Size	NDC	Benzoyl Peroxide	Active Erythromycin Powder (In Plastic	70% Ethyl Alcohol
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(Net weight)	NDC	Gel	Powder (in Plastic Vial)	To Be Added
23.3 grams (as dispensed)	64980-328-01	20 grams	0.8 grams	3 mL
46.6 grams (as dispensed)	64980-328-02	40 grams	1.6 grams	6 mL

Pharmacist Important - Prior to dispensing, tap vial until all powder flows freely. Add indicated amount of room temperature 70% ETHYL ALCOHOL to vial (to the mark) and immediately shake vigorously to completely dissolve erythromycin, then immediately add this solution to gel and stir until homogeneous in appearance (1 to 1-1/2 minutes). Erythromycin and Benzoyl Peroxide Topical Gel USP should then be stored under refrigeration. Do not freeze. Place a 3-month expiration date on the label.

Note: Prior to reconstitution, store at room temperature between 15° and 30° C (59°-86° F).

After reconstitution, store under refrigeration between 2° and 8° C (36°-46° F).

Do not freeze. Keep tightly closed. Keep out of the reach of children.

Rx only

Manufactured by: Lyne Laboratories, Inc., Brockton, MA 02301

Manufactured for: Rising Pharma Holdings, Inc., East Brunswick, NJ 08816

Revised: 08/2025

PIR32846-00

——PRINCIPAL DISPLAY PANEL 23.3g——

Rising®

NDC 64980-328-23

**Erythromycin and
Benzoyl Peroxide
Topical Gel USP**

FOR TOPICAL USE ONLY

Rx only

One 23.3g Jar (as dispensed)



NDC 64980-328-23

Erythromycin and Benzoyl Peroxide Topical Gel USP

For Topical Use Only **Rx only**

One 23.3g Jar (as dispensed)

After reconstitution, each gram of Erythromycin and Benzoyl Peroxide Topical Gel USP contains 30mg (3%) erythromycin and 50mg (5%) benzoyl peroxide in a base of purified water USP, carbomer 940 NF, ethyl alcohol 20%, sodium hydroxide NF, docusate sodium and fragrance. **Usual Dosage:** Apply twice daily, morning and evening, or as directed by physician to affected areas after skin is thoroughly washed, rinsed with warm water and gently patted dry. See package insert for full prescribing information. **WARNING: For external use only. KEEP AWAY FROM EYES. Keep out of reach of children. May bleach fabric or hair. Use within 3 months after mixing. Store mixed formulation under refrigeration between 2°-8°C (36°-46°F).**

Do not freeze. Keep tightly closed.

Mfd. by: Lyne Laboratories, Inc., Brockton, MA 02301

Revised: 08/2025

Mfd. for: Rising Pharma Holdings, Inc., East Brunswick, NJ 08816

LR32823-00

Lot No.:
Exp.:

Rising®

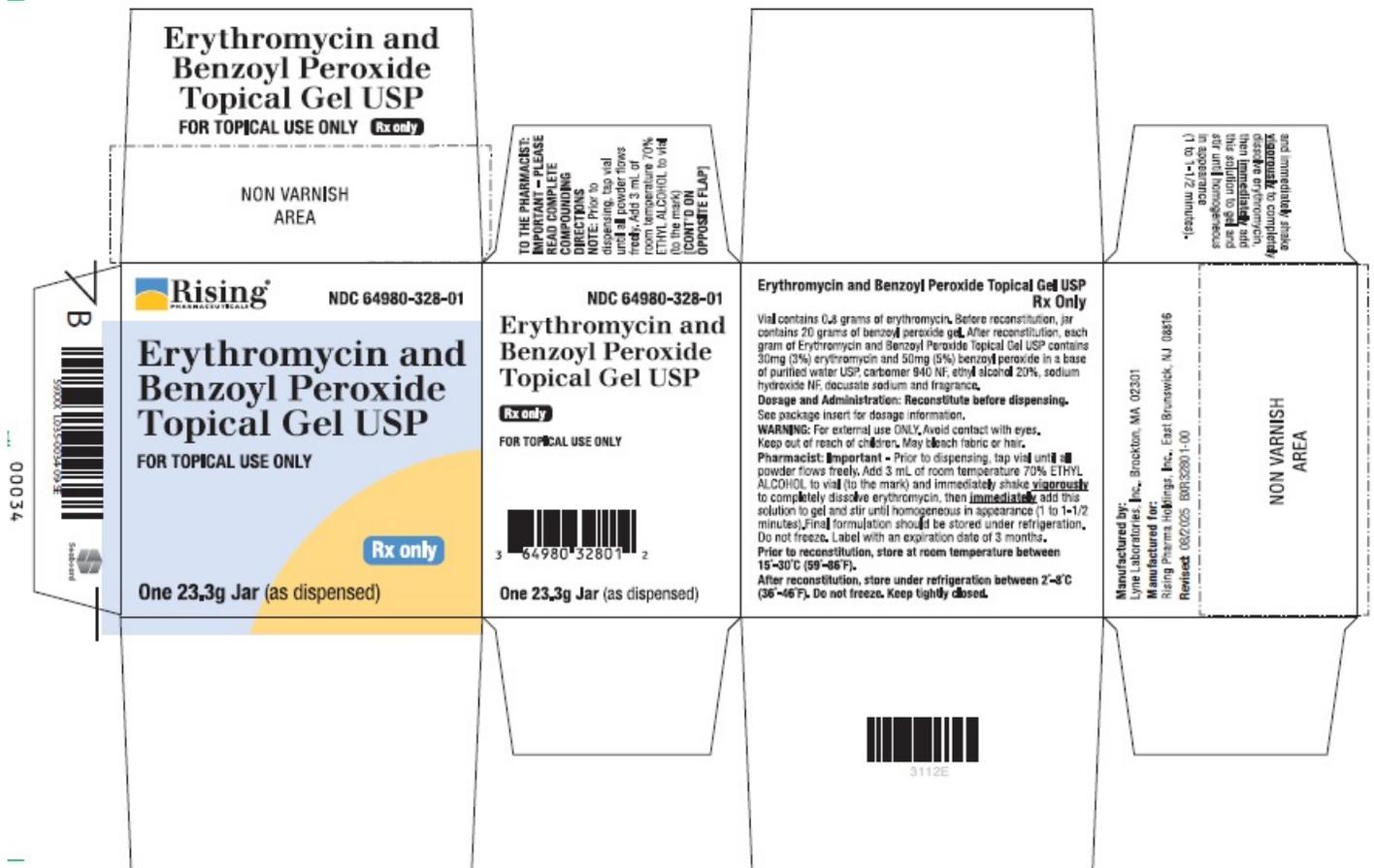
NDC 64980-328-01

Erythromycin and Benzoyl Peroxide Topical Gel USP

FOR TOPICAL USE ONLY

Rx only

One 23.3g Jar (as dispensed)



-----PRINCIPAL DISPLAY PANEL 46.6g-----

Rising®

NDC 64980-328-46

Erythromycin and Benzoyl Peroxide

Topical Gel USP
FOR TOPICAL USE ONLY

Rx only

One 46.6g Jar (as dispensed)

		NDC 64980-328-46	After reconstitution, each gram of Erythromycin and Benzoyl Peroxide Topical Gel USP contains 30mg (3%) erythromycin and 50mg (5%) benzoyl peroxide in a base of purified water USP, carbomer 940 NF, ethyl alcohol 20%, sodium hydroxide NF, docusate sodium and fragrance. Usual Dosage: Apply twice daily, morning and evening, or as directed by physician to affected areas after skin is thoroughly washed, rinsed with warm water and gently patted dry. See package insert for full prescribing information. WARNING: For external use only. KEEP AWAY FROM EYES. Keep out of reach of children. May bleach fabric or hair. Use within 3 months after mixing. Store mixed formulation under refrigeration between 2°-8°C (36°-46°F).	Revised: 08/2025 LR32846-00	Lot No: Exp.:
Erythromycin and Benzoyl Peroxide Topical Gel USP		For Topical Use Only Rx only One 46.6g Jar (as dispensed)	Do not freeze. Keep tightly closed. Mfd. by: Lyne Laboratories, Inc., Brockton, MA 02301 Mfd. for: Rising Pharma Holdings, Inc., East Brunswick, NJ 08816		

Rising®

NDC 64980-328-02

Erythromycin and Benzoyl Peroxide Topical Gel USP

FOR TOPICAL USE ONLY

Rx only

One 46.6g Jar (as dispensed)

<p>Erythromycin and Benzoyl Peroxide Topical Gel USP FOR TOPICAL USE ONLY Rx only</p> <p>NON VARNISH AREA</p>	<p>TO THE PHARMACIST: IMPORTANT - PLEASE DO NOT COMPLETE COMPONENTS INJECTION NOTE: Prior to dispensing, tap vial and allow to settle for 10 minutes. Store at room temperature 20°-25°C (68°-77°F). Do not freeze. ETHYL ALCOHOL, 20% (OPTIONAL FLAV)</p>		<p>Topical Gel USP contains 30mg (3%) erythromycin and 50mg (5%) benzoyl peroxide in a base of purified water USP, carbomer 940 NF, ethyl alcohol 20%, sodium hydroxide NF, docusate sodium and fragrance.</p>
<p> NDC 64980-328-02</p> <p>Erythromycin and Benzoyl Peroxide Topical Gel USP FOR TOPICAL USE ONLY Rx only</p> <p>One 46.6g Jar (as dispensed)</p>	<p>NDC 64980-328-02</p> <p>Erythromycin and Benzoyl Peroxide Topical Gel USP Rx only FOR TOPICAL USE ONLY</p> <p> 64980-32802</p> <p>One 46.6g Jar (as dispensed)</p>	<p>Erythromycin and Benzoyl Peroxide Topical Gel USP Rx Only</p> <p>Vial contains 1.6 grams of erythromycin, before reconstitution, jar contains 40 grams of benzoyl peroxide gel. After reconstitution, each gram of Erythromycin and Benzoyl Peroxide Topical Gel USP contains 30mg (3%) erythromycin and 50mg (5%) benzoyl peroxide in a base of purified water USP, carbomer 940 NF, ethyl alcohol 20%, sodium hydroxide NF, docusate sodium and fragrance.</p> <p>Dosage and Administration: Reconstitute before dispensing. See package insert for dosage information.</p> <p>WARNING: For external use ONLY. Avoid contact with eyes. Keep out of reach of children. May bleach fabric or hair.</p> <p>Pharmacist Important: Prior to dispensing, tap vial until all powder flows free. Add 8 mL of room temperature 70% ETHYL ALCOHOL to vial (to the mark) and immediately shake vigorously to completely dissolve erythromycin, then immediately add this solution to gel and stir until homogeneity in appearance (1 to 2/2 minutes). Final formulation should be stored under refrigeration. Do not freeze. Label with an expiration date of 3 months. Prior to reconstitution, store at room temperature between 15-30°C (59-86°F). After reconstitution, store under refrigeration between 2°-8°C (36-46°F). Do not freeze. Keep tightly closed.</p> <p>Manufactured by: Lyne Laboratories, Inc. Brockton, MA 02301</p> <p>Manufactured for: Rising Pharma Holdings, Inc., East Brunswick, NJ 08816</p> <p>Revised: 08/2025 00328002-00</p> <p>NON VARNISH AREA</p>	<p>3113E</p>

ERYTHROMYCIN AND BENZOYL PEROXIDE

erythromycin and benzoyl peroxide gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:64980-328
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ERYTHROMYCIN (UNII: 63937KV33D) (ERYTHROMYCIN - UNII:63937KV33D)	ERYTHROMYCIN	30 mg in 1 g
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALCOHOL (UNII: 3K9958V90M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64980-328-01	23.3 g in 1 JAR; Type 0: Not a Combination Product	10/18/2016	
2	NDC:64980-328-02	46.6 g in 1 JAR; Type 0: Not a Combination Product	10/18/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065385	10/18/2016	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Establishment

Name	Address	ID/FEI	Business Operations
Lyne Laboratories, Inc.		053510459	MANUFACTURE(64980-328)

