

DR. LIN SKINCARE ACNE- benzoyl peroxide lotion
DR LIN SKINCARE

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ACTIVE INGREDIENT

BENZOYL PEROXIDE 2.5%

PURPOSE

ACNE TREATMENT

WARNINGS

FOR EXTERNAL USE ONLY

DO NOT USE THIS MEDICATION IF YOU HAVE VERY SENSITIVE SKIN OR IF YOU ARE SENSITIVE TO BENZOYL PEROXIDE.

ASK A DOCTOR OR PHARMACIST BEFORE USE IF YOU ARE USING OTHER TOPICAL ACNE MEDICATIONS AT THE SAME TIME OR IMMEDIATELY FOLLOWING USE OF THIS PRODUCT. THIS MAY INCREASE THE DRYNESS OR IRRITATION OF THE SKIN. IF THIS OCCURS, ONLY ONE MEDICATION SHOULD BE USED UNLESS DIRECTED BY A DOCTOR.

WHEN USING THIS PRODUCT

- AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE THOROUGHLY WITH WATER.
- KEEP AWAY FROM LIPS AND MOUTH.
- AVOID UNNECESSARY SUN EXPOSURE AND USE A SUNSCREEN.

STOP USE AND ASK A DOCTOR IF SKIN IRRITATION OCCURS.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

USE FOR THE TREATMENT OF ACNE

DIRECTIONS

- USE TWICE DAILY AM AND PM.
- AFTER CLEANSING, APPLY TO ENTIRE FACE AVOIDING THE EYE AREA.
- DO NOT RINSE.
- ALLOW TO DRY.
- IF GOING OUTSIDE, USE A SUNSCREEN. IF EXCESSIVE DRYNESS OR BOTHERSOME PEELING OCCURS, REDUCE APPLICATION USE.

OTHER INFORMATION

- THIS PRODUCT MAY BLEACH HAIR OR DYED FABRICS.
- STORE AT ROOM TEMPERATURE.
- AVOID STORING AT EXTREME TEMPERATURES (BELOW 40°F AND ABOVE 100°F).

INACTIVE INGREDIENTS

WATER, GLYCERIN, POLYACRYLAMIDE, C13-14 ISOPARAFFIN, LAURETH-7, ARBUTIN, KOJIC ACID, L-ASCORBIC ACID, SODIUM PCA, ALLANTOIN, PANTHENOL, HYDROGENATED METHYL ABIETATE, PHENOXYETHANOL, FRAGRANCE, METHYLISOTHIAZOLINONE



2 Acne Lotion

Benzoyl Peroxide
Acne Treatment

NET WT 2 FL OZ (60 mL)

Active Ingredient: Benzoyl Peroxide 2.5%

Use: for the treatment of acne

Directions: Cleanse the skin thoroughly before applying this product. Cover the entire affected area with a thin layer 1 to 3 times daily. Do not rinse. Because excessive drying of the skin may occur, start with 1 application daily, then gradually increase to 2 to 3 times daily if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day or every other day. **If going outside, use a sunscreen.**

Warnings: For external use only. Do not use • If you have very sensitive skin or are sensitive to Benzoyl Peroxide. **Ask a doctor or pharmacist before use** • If you are using other topical acne drugs at the same time or right after use of this product. **When using this product** • avoid unnecessary sun exposure and use a sunscreen. • avoid contact with the eyes, lips and mouth • skin irritation may occur, characterized by redness, burning, itching, peeling or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration **Stop use and ask a doctor** if irritation becomes severe. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Other Information • sensitivity test: apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated. • avoid contact with hair and dyed fabrics, which may be bleached by this product. • Store at 60°F - 90°F.

See carton for more information.

Questions or Comments? 1-877-445-4624 Mon-Fri 8AM - 5PM (PST)

Distributed by Dr Lin Skin Care, Inc., • Beverly Hills, CA 90210

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Acne Lotion

Drug Facts

Active ingredient	Purpose
Benzoyl Peroxide 2.5%.....	Acne treatment

Use for the treatment of acne

Warnings For external use only

Do not use this medication if you have very sensitive skin or if you are sensitive to benzoyl peroxide.

Ask a doctor or pharmacist before use if you are using other topical acne medications at the same time or immediately following use of this product. This may increase the dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.

When using this product • avoid contact with eyes. If contact occurs, rinse thoroughly with water. • keep away from lips and mouth. • avoid unnecessary sun exposure and use a sunscreen.

Stop use and ask a doctor if skin irritation occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • Use twice daily AM and PM. • After cleansing, apply to entire face avoiding the eye area. • Do not rinse. • Allow to dry. • **If going outside, use a sunscreen.** If excessive dryness or bothersome peeling occurs, reduce application use.

Other Information • This product may bleach hair or dyed products. • **Store at room temperature.** Avoid storing at extreme temperatures (below 40° F and above 100° F).

Inactive ingredients Water, Glycerin, Polyacrylamide, C-13-14 Isoparaffin, Laureth-7, Arbutin, Kojic Acid, L-Ascorbic Acid, Sodium PCA, Allantoin, Panthenol, Hydrogenated Methyl Abletate, Phenoxyethanol, Fragrance, Methylisothiazolinone

DR. LIN SKINCARE ACNE

benzoyl peroxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58876-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	2.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
ARBUTIN (UNII: C5INA23HXF)	
KOJIC ACID (UNII: 6K23F1TT52)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
ALLANTOIN (UNII: 344S277G0Z)	
PANTHENOL (UNII: WV9CM0O67Z)	
GLYCERYL ABIETATE (UNII: 2F22LY70Q1)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58876-104-12	60 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	06/26/2013	

Labeler - DR LIN SKINCARE (622329980)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 6/2013

DR LIN SKINCARE