

INTENSIVE FACE AND BODY ACNE TREATMENT- benzoyl peroxide gel 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

BENZYL PEROXIDE 10%

PURPOSE

ACNE TREATMENT

USE

FOR THE TREATMENT OF ACNE AND ACNE DARK AND RED MARKS.

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 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 unnecessary sun exposure and use a sunscreen.
- avoid contact with eyes lips and mouth.
- avoid contact with hair and dyed fabrics, which may be bleached by this product.
- 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 PRODUCT IS SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

Directions

- wet area to be cleansed.
- apply small amount to skin.
- gently massage to create lather.
- rinse thoroughly and pat dry.
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to twice daily if needed or directed by a doctor.
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day. If going outside, apply sunscreen after using this product.

Other information

- sensitivity test for new users: 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.

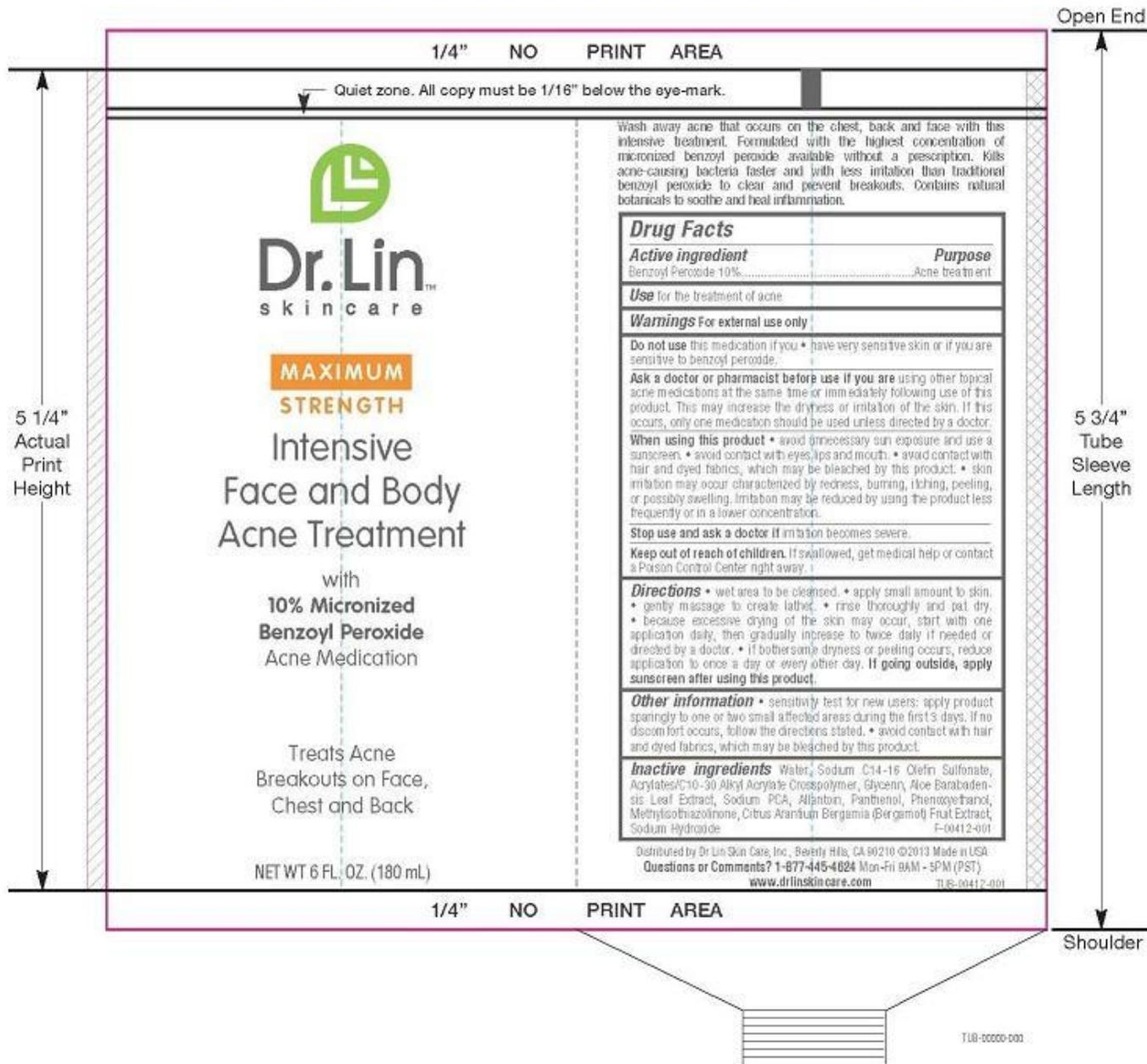
INACTIVE INGREDIENTS

Water, Sodium C14-16 Olefin Sulfonate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Glycerin, Aloe Barabadsensis Leaf Extract, Sodium PCA, Allantoin, Panthenol, Phenoxyethanol, Methylisothiazolinone, Citrus Arantium Bergamia (Bergamot) Fruit Extract, Sodium Hydroxide

QUESTIONS OR COMMENTS?

1-877-445-4624

MON-FRI 8AM - 5PM (PST)



INTENSIVE FACE AND BODY ACNE TREATMENT

benzoyl peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58876-107
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
ALLANTOIN (UNII: 344S277G0Z)	
PANTHENOL (UNII: WV9CM0O67Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
BERGAMOT ORANGE (UNII: IET5D90X0D)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58876-107-36	180 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	07/11/2014	

Labeler - DR LIN SKINCARE (622329980)**Establishment**

Name	Address	ID/FEI	Business Operations
Westwood Laboratories Inc.		069926483	manufacture(58876-107) , pack(58876-107)

Revised: 7/2014

DR LIN SKINCARE