

ACNE SOLUTIONS EMERGENCY- benzoyl peroxide lotion
CLINIQUE LABORATORIES INC

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 0.5%

water [] c12-15 alkyl benzoate [] glycerin [] cetearyl alcohol [] steareth-2 [] sucrose [] steareth-20 [] polyacrylamide [] dimethicone [] glyceryl stearate [] peg-100 stearate [] acetyl glucosamine [] camellia sinensis leaf extract [] caffeine [] yeast extract (faex) [] cola nitida extract [] laminaria saccharina extract [] sea whip extract [] c13-14 isoparaffin [] butylene glycol [] laureth-7 [] chloroxylenol [] phenoxyethanol

USES:

- TREATS ACNE
- CLEARS ACNE BLEMISHES
- HELPS PREVENT DEVELOPMENT OF NEW ACNE BLEMISHES

WARNING: FOR EXTERNAL USE ONLY

DO NOT USE IF YOU

- HAVE VERY SENSITIVE SKIN
- ARE SENSITIVE TO BENZOYL PEROXIDE

WHEN USING THIS PRODUCT

- SKIN IRRITATION AND DRYNESS IS MORE LIKELY TO OCCUR IF YOU USE ANOTHER TOPICAL ACNE MEDICATION AT THIS TIME. IF IRRITATION OCCURS, USE ONLY ONE TOPICAL ACNE MEDICATION AT AT TIME
- AVOID UNNECESSARY SUN EXPOSURE AND USE A SUNSCREEN
- AVOID CONTACT WITH THE 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 SWALLOWED, GET MECICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS:

- CLEANS SKIN THOROUGHLY BEFORE APPLYING THIS PRODUCT
- COVER THE ENTIRE AFFECTED AREA WITH A THIN LAYER ONE TO THREE TIMES DAILY
- BECAUSE EXCESSIVE DRYING OF THE SKIN MAY OCCUR, START WITH ONE APPLICATION DAILY, THEN GRADUALLY INCREASE TO TWO OR THREE TIMES DAILY IF NEEDED OR AS DIRECTED BY A DOCTOR
- IF BOTHERSOME DRYNESS OR PEELING OCCURS, REDUCE APPLICATION TO ONCE A DOY OR EVERY OTHER DAY

- IF GOING OUTSIDE, USE A SUNSCREEN AFTER APPLYING THIS PRODUCT. IF IRRITATION OR SENSITIVITY DEVELOPS, DISCONTINUE USE OF BOTH PRODUCTS AND CONSULT A DOCTOR
- FOR BEST RESULTS, USE AFTER ACNE SOLUTIONS CLEANSING FOAM AND CLARIFYING LOTION

COVER THE ENTIRE AFFECTED AREA WITH A THIN LAYER ONE TO THREE TIMES DAILY

PRINCIPAL DISPLAY PANEL:
CLINIQUE

ACNE SOLUTIONS

EMERGENCY

GEL-LOTION

BENZOYL PEROXIDE

ACNE MEDICATION

ALL SKIN TYPES

0.5 FL OZ LIQ. / 15 ML

CLINIQUE LABORATORIES DIST
NEW YORK, NEW YORK 10022

Drug Facts (continued)

• Avoid unnecessary sun exposure and use a sunscreen • Avoid contact with the 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 swallowed, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions • cleanse skin thoroughly before applying this product • cover the entire affected area with a thin layer one to three times daily • because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three 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 after applying this product. If irritation or sensitivity develops, discontinue use of both products and consult a doctor.

Inactive ingredients water (aqua purificata) purified • c12-15



Drug Facts (continued)

alkyl benzoate • glycerin • cetearyl alcohol • steareth-2 • sucrose • steareth-20 • polyacrylamide • dimethicone • glyceryl stearate • peg-100 stearate • acetyl glucosamine • camellia sinensis (green tea) leaf extract • caffeine • yeast extract (faex) • cola nitida (kola) extract • laminaria saccharina extract • sea whip extract • c13-14 isoparaffin • butylene glycol • laureth-7 • chloroxylenol • phenoxyethanol [In2275B].

5 FL. OZ. / 150 mL
ALL SKIN TYPES
Tous types de peau
BENZOYL PEROXIDE
ACNE MEDICATION
e

CLINIQUE
acne
solutions
emergency
gel-lotion
intensif



Drug Facts

Active ingredient	Purpose
Benzoyl peroxide 5.0%	Acne treatment

Uses

• treats acne • clears acne blemishes
• helps prevent development of new acne blemishes

Drug Facts (continued)

Warnings
For external use only.

Do not use if you • Have very sensitive skin • Are sensitive to benzoyl peroxide
When using this product • Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.

ACNE SOLUTIONS EMERGENCY

benzoyl peroxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-718
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 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
STEARETH-2 (UNII: V56DFE46J5)	
SUCROSE (UNII: C151H8M554)	
STEARETH-20 (UNII: L0Q8IK9E08)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CAFFEINE (UNII: 3G6A5W338E)	
YEAST (UNII: 3NY3SM6B8U)	
COLA NITIDA SEED (UNII: PQM9SA369U)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
LAURETH-7 (UNII: Z95S6G8201)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-718-01	1 in 1 CARTON		
1	NDC:49527-718-02	15 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	12/01/2000	

Labeler - CLINIQUE LABORATORIES INC (173047747)**Establishment**

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		205952385	manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
Len-Ron Manufacturing Division of Aramis Inc.		809771152	manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
Aramis Inc.		042918826	manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
Northtec Bristol		949264774	manufacture, relabel, repack

Establishment			
Name	Address	ID/FEI	Business Operations
Northtec Keystone		618107429	manufacture, relabel, repack

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2		828534516	manufacture, relabel, repack

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd.		255175580	manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics, Ltd		253616536	manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics Distribution Center		208579636	repack, relabel

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Kabushiki Kaisha		712808195	relabel, repack

Establishment			
Name	Address	ID/FEI	Business Operations
Whitman Laboratories Ltd.		216866277	manufacture

Establishment			
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Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
CONTRACT PHARMACEUTICALS		248 76 1249	manufacture

Revised: 7/2011

CLINIQUE LABORATORIES INC