ACNE CLEANSING- salicylic acid gel CLINIQUE LABORATORIES LLC

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.

ACNE SOLUTIONS CLEANSING GEL

Drug Facts

Active Ingredient

Salicylic Acid 2%

Purpose

Acne Treatment

Uses

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

Warnings

For external use only

When using this product using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.

Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Wet hands and work into a lather
- Add water to increase lather
- Massage gently over wet skin, avoiding eye area
- Rinse
- Use A.M. and P.M.
- If bothersome drying or peeling occurs, reduce usage to every other day
- Follow with Acne Solutions Clarifying Lotion

Inactive ingredients

water\aqua\eau • glycerin • sodium laureth sulfate • sodium chloride • lauramidopropyl betaine • butylene glycol • sucrose • gentiana lutea (gentian) root extract • laminaria saccharina extract • caffeine • sodium hyaluronate • acetyl glucosamine • laureth-2 • peg-120 methyl glucose dioleate • sodium sulfate • benzophenone-4 • sodium hydroxide • edta • disodium edta • bht • phenoxyethanol • blue 1 (ci 42090) [iln41073]

Other information

Protect the product in this container from excessive heat and direct sun

PRINCIPAL DISPLAY PANEL - 125 mL Tube Carton

acne

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CLINIQUE

acne solutions

cleansing gel

SALICYLIC ACID ACNE MEDICATION

ALL SKIN TYPES

4.2 FL.OZ.LIQ./125 ml e

acne

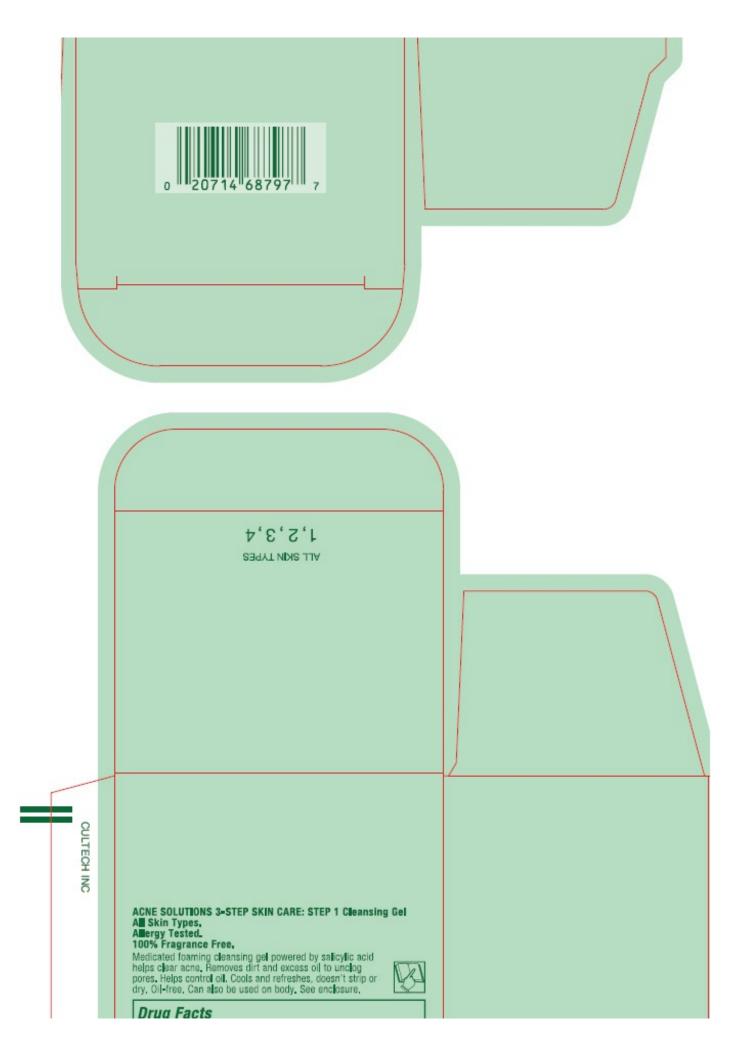
CLINIQUE

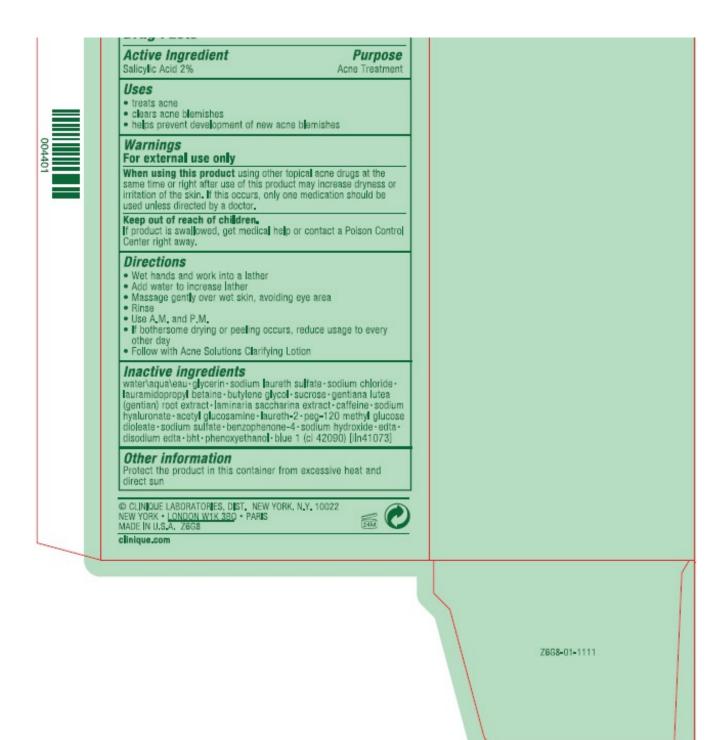
acne solutions cleansing gel

> SALICYLIC ACID ACNE MEDICATION

ALL SKIN TYPES

4.2 FL.0Z.LIQ./125 ml &





ACNE CLEANSING

salicylic acid gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-045
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LP	Z) SALICYLIC ACID	0.02158 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
LAURAMIDO PRO PYL BETAINE (UNII: 23D6 XVI233)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SUCROSE (UNII: C151H8M554)	
GENTIANA LUTEA ROOT (UNII: S72O3284MS)	
SACCHARINA LATISSIMA (UNII: 68CMP2MB55)	
CAFFEINE (UNII: 3G6A5W338E)	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	
N-ACETYLGLUCO SAMINE (UNII: V956696549)	
LAURETH-2 (UNII: D4D38LT1L5)	
PEG-120 METHYL GLUCO SE DIOLEATE (UNII: YM0 K64F20 V)	
SODIUM SULFATE (UNII: 0 YPR65R21J)	
SULISOBENZONE (UNII: 1W6L629B4K)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETIC ACID (UNII: 9G34HU7RV0)	
EDETATE DISO DIUM (UNII: 7FLD91C86K)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
PHENO XYETHANOL (UNII: HIE492ZZ3T)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:49527-045-01	1 in 1 CARTON	10/01/2014	
1	125 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Inform	nation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333D	10 / 0 1 / 20 14	

Labeler - CLINIQUE LABORATORIES LLC (044475127)

Establishment				
Name	Address	ID/FEI	Business Operations	
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(49527-045), REPACK(49527-045)	

Establishment				
Name	Address	ID/FEI	Business Operations	
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-045)	

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(49527-045)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-045)

Establishment			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-045)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(49527-045), REPACK(49527-045)

Establishment					
Name	Address	ID/FEI	Business Operations		
PADC 1		949264774	RELABEL(49527-045), REPACK(49527-045)		

Establishment					
Name	Address	ID/FEI	Business Operations		
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-045)		

Establishment					
Name	Address	ID/FEI	Business Operations		
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49527-045)		

Revised: 11/2019 CLINIQUE LABORATORIES LLC