

CLEAR PROOF CLARIFYING CLEANSING GEL ACNE MEDICATION- salicylic acid gel

Mary Kay 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.

Clear Proof Clarifying Cleansing Gel Drug Facts

Active ingredient

Salicylic Acid (2% W/W)

Purpose

Acne Medication

Uses

- for the management of acne
- helps prevent new acne pimples

Warnings

For external use only

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.
- avoid contact with the eyes

Stop use and ask a doctor if

irritation or sensitivity develops or increases

Keep out of reach of children.

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

Directions

- cleanse skin thoroughly before applying medication
- cover the entire affected area with a thin layer and rinse thoroughly 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

Inactive ingredients

arctium lappa root extract, butylene glycol, citric acid, cocamidopropyl betaine, cystoseira amentacea/caespitosa branchycarpa extract, disodium EDTA, DMDM hydantoin, epilobium angustifolium flower/leaf/stem extract, ethylparaben, glycerin, methylparaben, phenoxyethanol, propylene glycol, propylparaben, sodium C14-16 olefin sulfonate, sodium chloride, triethanolamine, water

Principal Display Panel - 127 g carton

clearproof

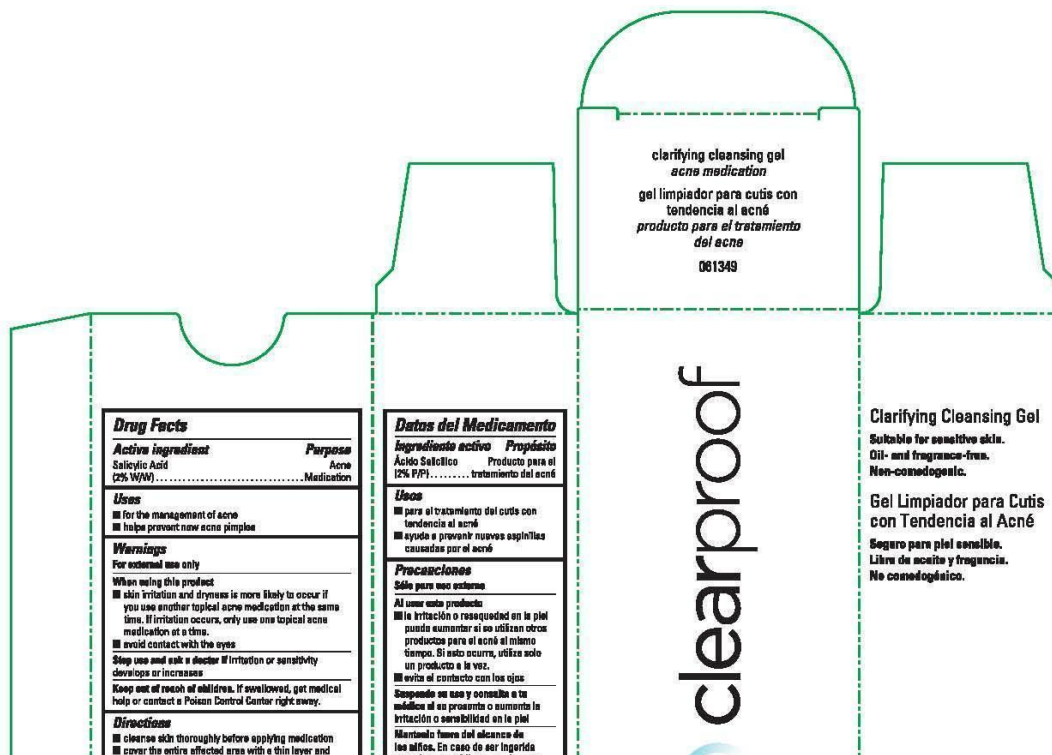
clarifying cleansing gel

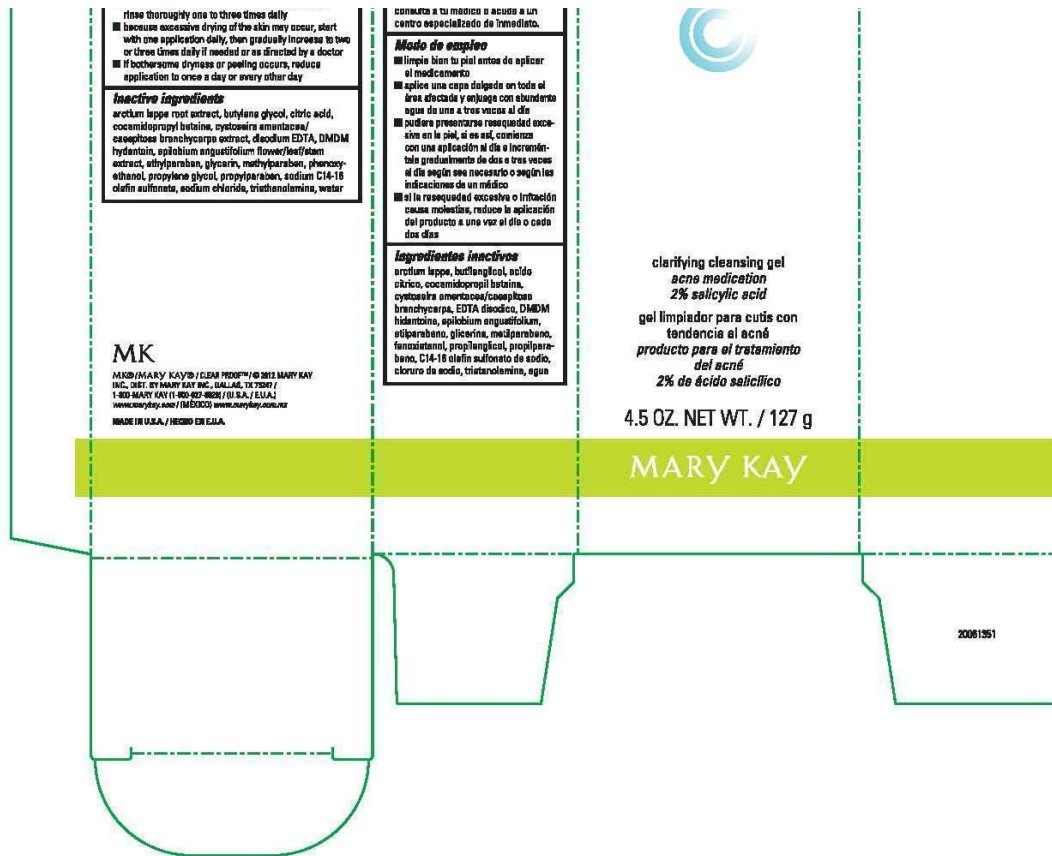
acne medication

2% salicylic acid

4.5 OZ. NET WT. / 127 g

Mary Kay





CLEAR PROOF CLARIFYING CLEANSING GEL ACNE MEDICATION

salicylic acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51531-1349
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: 0414PZ4LPZ) (SALICYLIC ACID - UNII:0414PZ4LPZ)	SALICYLIC ACID	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	

SODIUM CHLORIDE (UNII: 451W47IQ8X)
TROLAMINE (UNII: 9O3K93S3TK)
EDETATE DISODIUM (UNII: 7FLD91C86K)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
METHYLPARABEN (UNII: A2I8C7HI9T)
ETHYLPARABEN (UNII: 14255EXE39)
DMDM HYDANTOIN (UNII: BYR0546TOW)
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
GLYCERIN (UNII: PDC6A3C0OX)
EPILOBIUM ANGUSTIFOLIUM FLOWERING TOP (UNII: 08H094218D)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51531-1349-4	1 in 1 CARTON	08/15/2013	
1		127 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51531-1349-1	28 g in 1 TUBE; Type 0: Not a Combination Product	08/15/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	08/15/2013	

Labeler - Mary Kay Inc. (049994452)

Establishment

Name	Address	ID/FEI	Business Operations
Port Jervis Laboratories Inc.		001535103	manufacture(51531-1349)

Establishment

Name	Address	ID/FEI	Business Operations
Englewood Lab Inc.		172198223	pack(51531-1349)

Establishment

Name	Address	ID/FEI	Business Operations
Mary Kay Inc.		103978839	manufacture(51531-1349)