EPHIDERM SPOT TREATMENT- salicylic acid lotion
KANTIAN SKINCARE, 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.

Active Ingredient:

Salicylic acid 1.0%

Uses:

Treats and helps prevent acne blemishes

Warnings:

For external use only. Avoid contact with eyes. If contact occurs, flush thoroughly with water. Using other topical acne medications at the same time or right after use of this product may increase skin dryness or irritation. Avoid doing this, unless directed by a doctor. Avoid unnecessary sun exposure and use sunscreen. Allow epHiderm Spot Treatment to dry, then follow the sunscreen directions. Do not use this product if you have sensitive skin or if you are sensitive to AHAs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately. Do not use this product on infants under 6 months of age.

Directions:

Apply a thin layer to the affected area, In the morning and evening. For best results, apply epHiderm Synergyzer after epHiderm Spot Treatment. Wash hands thoroughly after application.

Inactive Ingredients:

Water, Isopropyl alcohol, Propylene glycol, Hydroxyethylcellulose, Mandelic acid, Methyloxirane, Oxirane, Sodium benzoate, FD&C Blue #1

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Principal Display Panel – Tube Label

epHiderm

ANTI-ACNE SOLUTION
SPOT TREATMENT

Eliminates acne causing bacteria
Clears acne pimples and blackheads quickly
Gentle enough for everyday use

Dermatologist Recommended

MADE IN USA

NET WT. 1 OZ (28g)

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salicylic acid lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57524-013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	1.0 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Isopropyl Alcohol (UNII: ND2M416302)	
Propylene Glycol (UNII: 6DC9Q167V3)	
HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) (UNII: S38J6RZN16)	
Mandelic Acid (UNII: NH496X0UJX)	
Sodium Benzoate (UNII: OJ245FE5EU)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
Propylene Oxide (UNII: Y4Y7NYD4BK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57524-013-01	28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358B	01/10/2013	

Labeler - KANTIAN SKINCARE, LLC (078436984)

Establishment

Name	Address	ID/FEI	Business Operations
Kantian Skincare, LLC		078436984	LABEL(57524-013)

Establishment

Name	Address	ID/FEI	Business Operations
PhytogenX, Inc		010297942	MANUFACTURE(57524-013)

Revised: 4/2013 KANTIAN SKINCARE, LLC