MD ACNE CUSTOMIZED TREATMENT- salicylic acid cream MDalgorithms 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.

MD ACNE Customized Treatment Cream

DRUG FACTS:

Active Ingredient:

Salicylic Acid 2.00%

Acne Treatment

Use For:

For the treatment of Acne. Clears up acne pimples and blemishes, and allows skin to heal. Helps prevent new pimples and blemishes from forming.

Warnings:

- For external use only.
- Using other topical acne medications the same time or immerdiately following use of this product may increase dryness or irritation of the skin.
- Because excessive drying of the skin may occur, start with one daily. Gradually increase to two
 times daily if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce
 application to once per day.

Do not use

for prolonged periods without consulting a doctor.

Keep out of reach of children.

If swallowed, contact physician or poison control center immediately.

Store at room temperature

Directions:

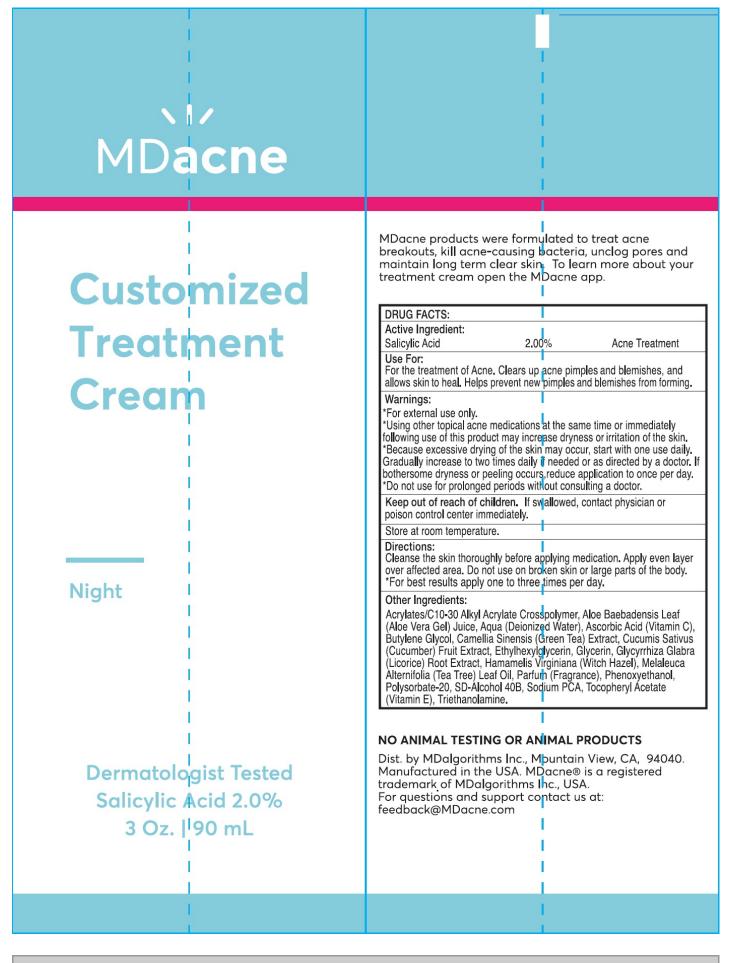
Cleanse the skin thoroughly before applying medication. Apply even layer over affected area. Do not use on broken skin or large parts of the body.

• For best results apply one to three times per day.

Other Ingredients:

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Baebadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Ascorbic Acid (Vitamin C), Butylene Glycol, Camellia Sinensis (Green Tea) Extract, Cucumis Sativus (Cucumber) Fruit Extract, Ethylhexylglycerin, Glycerin, Glycyrrhiza Glabra (Licorice) Root Extract, Hamamelis Virginiana (witch Hazel), Melaleuca Alternifolia (Tea Tree) Leaf Oil, Parfum (Fragrance), Phenoxyethanol, Polysorbate-20, SD-Alcohol 40B, Sodium PCA, Tocopheryl Acetate (Vitamin E), Triethanolamine.

Package	Labeling:
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salicylic acid cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71804-854
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	20 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
WATER (UNII: 059QF0KO0R)		
ASCORBIC ACID (UNII: PQ6 CK8 PD0 R)		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
GREEN TEA LEAF (UNII: W2ZU1RY8B0)		
CUCUMBER (UNII: YY7C30VXJT)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
GLYCERIN (UNII: PDC6A3C0OX)		
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)		
TEA TREE OIL (UNII: VIF565UC2G)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
SO DIUM PYRROLIDONE CARBO XYLATE (UNII: 469 OTG57A2)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)		
TROLAMINE (UNII: 903K93S3TK)		

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:71804-854-00	90 mL in 1 TUBE; Type 0: Not a Combination Product	10/12/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	10/12/2017	

Labeler - MDalgorithms Inc (080479826)

Revised: 10/2017 MDalgorithms Inc