NUVILEO SKIN PERFECTING ACNE- salicylic acid cream Cosmetic Specialty Labs, 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.

Nuviléo™ Skin Perfecting Acne Cream

Drug Facts

Active Ingredient

Salicylic Acid 2%

Purpose

Acne Treatment

Uses

for treatment of acne

Warnings

for external use only

Ask a doctor if you are using other topical acne medications at the same time or immediately following use of this product. If increased dryness or irritation occurs, only one medication should be used, unless directed by a doctor.

Avoid contact with eyes. If contact occurs, flush thoroughly with water.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

Apply thin layer of cream on affected skin surface.

Inactive ingredients

Allantoin, Aloe Barbadensis Leaf, Aloe barbadensis mill, C13-14 Isoparaffin, Caprylyl Glycol, Citrus Grandis (Grapefruit) Peel Oil, Cyclomethicone, Disodium EDTA, Emulsifying Wax, Ethylhexyl Stearate, Hydrastis canadensis L., Laureth-7, Olea Europaea (Olive) Fruit Oil, Panax quinquefolius L., Passiflora Incarnata, Phenoxyethanol, Polyacrylamide, Purified Water, Sorbitol, Tocopheryl Acetate, Triethanolamine

PRINCIPAL DISPLAY PANEL - 60 ml Tube Label

Nuvilé o TM

Skin Perfecting Acne Cream

Residue free acne cream for

Clear Skin Everyday

- Reduces redness
- Clears breakouts
- Hydrates, soothes & repairs

Salicylic Acid Acne Treatment 2 FL. OZ. / 60 ml.

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Nuviléo Skin Perfecting Acne Cream is scientifically formulated to clear facial and body acne blemishes as well as keep skin clear and revitalized.

NuVision Pharmaceuticals, LLC. 4651 Roswell Rd., Suite G-601 Atlanta, GA 30342 www.nuvileo.com Toll-free: 1-888-252-6208 Made in USA NUV2424010



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Salicylic Acid Acne Treatment 2 FL OZ / 60 ml

NUVILEO SKIN PERFECTING ACNE

salicylic acid cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:58 133-500

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	
Allantoin (UNII: 344S277G0Z)		
Aloe Vera Leaf (UNII: ZY81Z83H0X)		
Aloe Vera Whole (UNII: KIZ4X2EHYX)		
C13-14 Isoparaffin (UNII: E4F12ROE70)		
Caprylyl Glycol (UNII: 00 YIU5438 U)		
Citrus Maxima Fruit Rind Oil (UNII: 8U3877WD44)		
Cyclomethicone (UNII: NMQ347994Z)		
Edetate Disodium (UNII: 7FLD91C86K)		
Ethylhexyl Stearate (UNII: EG3PA2K3K5)		
Hydrastis Canadensis Whole (UNII: R763EBH88T)		
Laureth-7 (UNII: Z95S6G8201)		
Olive Oil (UNII: 6UYK2W1W1E)		
Panax Quinquefolius Whole (UNII: 0P067WOA1X)		
Passiflora Incarnata Flowering Top (UNII: CLF5YFS11O)		
Phenoxyethanol (UNII: HIE492ZZ3T)		
Water (UNII: 059QF0KO0R)		
Sorbitol (UNII: 506T60A25R)		
.AlphaTocopherol Acetate (UNII: 9E8X80D2L0)		
Trolamine (UNII: 9O3K93S3TK)		

l	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:58133-500-02	60 mL in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part333D	06/30/2015		

Labeler - Cosmetic Specialty Labs, Inc. (032973000)

Establishment				
Name	Address	ID/FEI	Business Operations	
Cosmetic Specialty Labs		032973000	MANUFACTURE(58133-500)	

Revised: 7/2015 Cosmetic Specialty Labs, Inc.