

**NUVILEO ACNE FACE WASH- salicylic acid solution, gel forming / drops**  
**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.*

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**Nuvió™ Acne Face Wash**

***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**

Use twice a day. Wet face, apply to hands, add water and work into a lather. Massage into your face, rinse.

**Inactive ingredients**

Aloe Barbados Mill, Caprylyl Glycol, Cocamidopropyl Betaine, Coco-Glucoside, Fragrance, Glyceryl Oleate, Hydrastis canadensis L., Lauramide D A, Lauryl Gucoside, Organic Greenhouse Grown Aloe Barbados Leaf, Panax quinquefolis L., Phenoxyethanol, Purified Water, Sodium Citrate, Sodium Lauryl Glucose Carboxylate.

**PRINCIPAL DISPLAY PANEL - 180 ml Bottle Label**

**Nuvió™**  
**Acne Face Wash**

Oil-free AM / PM cleanser for  
Clear Skin Everyday

## Non-Drying Formula

- Reduces redness
- Clears breakouts
- Gently exfoliates skin
- Removes excess oil, dirt & makeup

## Salicylic Acid Acne Treatment

6 FL. OZ. / 180 ml.

<p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active Ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Salicylic Acid 2%.....</td> <td>Acne Treatment</td> </tr> </tbody> </table> <p><b>Uses:</b> for treatment of acne</p> <p><b>Warnings:</b> for external use only</p> <p><b>Ask a doctor if you are using</b> 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.</p> <p><b>Avoid contact with eyes.</b> If contact occurs, flush thoroughly with water.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a poison control center right away.</p> <p><b>Directions:</b> Use twice a day. Wet face, apply to hands, add water and work into a lather. Massage into your face, rinse.</p> <p><b>Inactive ingredients</b> Aloe Barbadensis Mill, Caprylyl Glycol, Cocamidopropyl Betaine, Coco-Glucoside, Fragrance, Glyceryl Oleate, Hydrastis canadensis L., Lauramide D A, Lauryl Gucoside, Organic Greenhouse Grown Aloe Barbadensis Leaf, Panax quinquefolis L., Phenoxyethanol, Purified Water, Sodium Citrate, Sodium Lauryl Glucose Carboxylate.</p>	Active Ingredient	Purpose	Salicylic Acid 2%.....	Acne Treatment	<p><b>Nuviléo™</b> <b>Acne Face Wash</b></p> <p>Oil-free AM / PM cleanser for Clear Skin Everyday</p> <p>Non-Drying Formula</p> <ul style="list-style-type: none"> <li>▪ Reduces redness</li> <li>▪ Clears breakouts</li> <li>▪ Gently exfoliates skin</li> <li>▪ Removes excess oil, dirt &amp; makeup</li> </ul> <p>Salicylic Acid Acne Treatment 6 FL OZ / 180 ml</p>	<p><i>Nuviléo Acne Face Wash is scientifically formulated to clear facial and body acne.</i></p> <p>NuVision Pharmaceuticals, LLC. 4651 Roswell Rd., Suite G-601 Atlanta, GA 30342 www.nuvileo.com Toll-free: 1-888-252-6208 Made in USA NUV2424009</p>  <p>01 791102 555207</p>
Active Ingredient	Purpose					
Salicylic Acid 2%.....	Acne Treatment					

## NUVILEO ACNE FACE WASH

salicylic acid solution, gel forming / drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58 133-50 1
<b>Route of Administration</b>	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
<b>Aloe Vera Whole</b> (UNII: KIZ4X2EHYX)	
<b>Caprylyl Glycol</b> (UNII: 00YIU5438U)	
<b>Cocamidopropyl Betaine</b> (UNII: 5OCF3O11KX)	
<b>Coco Glucoside</b> (UNII: ICS790225B)	
<b>Glyceryl Oleate</b> (UNII: 4PC054V79P)	
<b>Hydrastis Canadensis Whole</b> (UNII: R763EBH88T)	
<b>Lauryl Glucoside</b> (UNII: 76LN7P7UCU)	
<b>Panax Quinquefolius Whole</b> (UNII: 0P067WOA1X)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Sodium Citrate</b> (UNII: 1Q73Q2JULR)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58 133-50 1-06	180 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58 133-50 1-03	90 mL in 1 BOTTLE; 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(58133-501)

Revised: 7/2015

Cosmetic Specialty Labs, Inc.