

# **PROSORIA PSORIASIS TREATMENT- salicylic acid gel**

## **Nuvothera, Inc.**

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### **Prosoria Psoriasis Treatment**

#### ***Drug Facts***

#### **Active ingredient**

Salicylic acid, 3%

#### **Purpose**

Antipsoriasis

#### **Uses**

relieves and helps prevent recurrence of psoriasis symptoms including:

- scaling
- flaking
- itching
- redness
- irritation

#### **Warnings**

##### **For external use only**

**When using this product** avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

**Stop use and consult a doctor** if the condition worsens or does not improve after regular use of this product as directed and/or if condition covers a large area of the body.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- apply to affected areas once daily or as directed by a doctor
- use in conjunction with the Prosoria Daily Psoriasis Treatment System.

#### **Other information**

- store at room temperature 59-77°F (15-25°C).

#### **Inactive ingredients**

Citric Acid, Curcuma Longa (Turmeric) Root Extract, Cyclodextrin, Disodium EDTA, Ethoxydiglycol, Polyacrylate Crosspolymer-6, Potassium Sorbate, Oleth-3 Phosphate, Sodium Hydroxide, Tetrahydrodiferuloylmethane, Water.

### **Questions?**

Visit [www.prosoria.com](http://www.prosoria.com) or call toll-free 1-833-776-7483 Mon - Fri, 8am - 5pm CT.

Distributed by Nuvothera, Inc.  
Fort Worth, TX 76104

### **PRINCIPAL DISPLAY PANEL - 59 mL Bottle Label**

prosoria

MAXIMUM  
STRENGTH

treats

psoriasis  
treatment gel  
3% salicylic acid

2 FL OZ (59mL)

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Salicylic acid, 3%	Antipsoriasis
<b>Uses</b> relieves and helps prevent recurrence of psoriasis symptoms including: • scaling • flaking • itching • redness • irritation	
<b>Warnings</b> <b>For external use only</b>	
<b>When using this product</b> avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.	
<b>Stop use and consult a doctor</b> if the condition worsens or does not improve after regular use of this product as directed and/or if condition covers a large area of the body.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • apply to affected areas once daily or as directed by a doctor • use in conjunction with the Prosoria Daily Psoriasis Treatment System.	
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## PROSORIA PSORIASIS TREATMENT

salicylic acid gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71573-102
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Salicylic Acid</b> (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	1.77 g in 59 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Diethylene Glycol Monoethyl Ether</b> (UNII: A1A1I8X02B)	
<b>Tetrahydrodiferuloylmethane</b> (UNII: 00U0645U03)	

<b>TURMERIC</b> (UNII: 856YO1Z64F)	
<b>GAMMA CYCLODEXTRIN</b> (UNII: KZJ0BYZ5VA)	
<b>Oleth-3 Phosphate</b> (UNII: 8Q0Z18J1VL)	
<b>Edetate Disodium Anhydrous</b> (UNII: 8NLQ36F6MM)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
<b>Potassium Hydroxide</b> (UNII: WZH3C48M4T)	
<b>Potassium Sorbate</b> (UNII: 1VPU26JZZ4)	
<b>Citric Acid Monohydrate</b> (UNII: 2968PHW8QP)	

### Product Characteristics

<b>Color</b>	WHITE (Off White Beige)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71573-102-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/22/2017	
2	NDC:71573-102-08	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M032	11/22/2017	

**Labeler** - Nuvothera, Inc. (080499864)

### Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO		080170933	MANUFACTURE(71573-102)