

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

**Nuvothera, 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.*

-----

### **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

**prosoriä**

treats

2

psoriasis treatment gel

3% salicylic acid

daily psoriasis

treatment system

2 FL OZ (59mL)

**Drug Facts**

Active Ingredient	Purpose
Salicylic acid, 3%	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.

Prosoria is a registered trademark of Nuvothera, Inc. Copyright 2017 Nuvothera, Inc.

Distributed by Nuvothera, Inc. Fort Worth, TX 76104 | Made in U.S.A. P08172

prosoriä

treats

2

psoriasis treatment gel  
3% salicylic acid

daily psoriasis  
treatment system

3 71573 10201 0

2 FL OZ (59mL)

## 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

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
Water (UNII: 059QF0K00R)	
Diethylene Glycol Monoethyl Ether (UNII: A1A18X02B)	
Tetrahydrodiferuloylmethane (UNII: 00U0645U03)	
TURMERIC (UNII: 856YO1Z64F)	
GAMMA CYCLODEXTRIN (UNII: KZJ0BYZ5VA)	
Oleth-3 Phosphate (UNII: 8Q0Z18J1VL)	
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Potassium Hydroxide (UNII: WZH3C48M4T)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
Citric Acid Monohydrate (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

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part358H	11/22/2017	

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

## Establishment

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

Revised: 2/2020

Nuvothena, Inc.