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 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

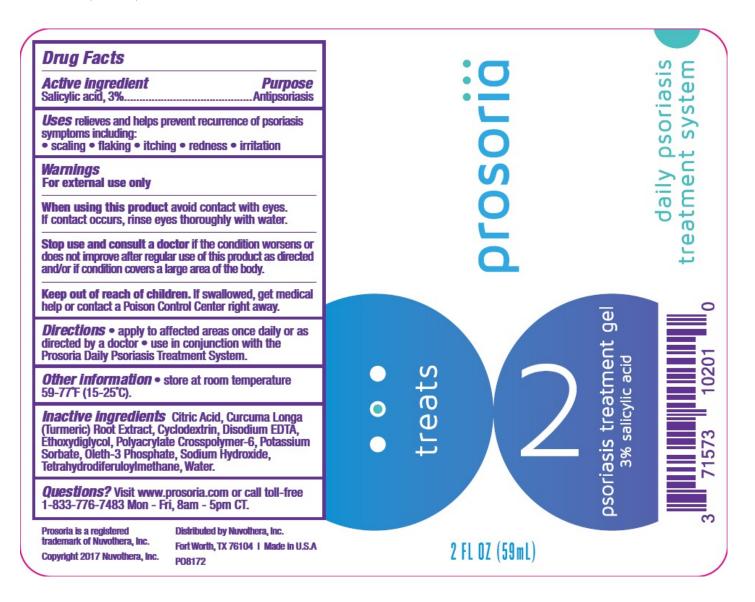
treats

2

psoriasis treatment gel 3% salicylic acid

daily psoriasis treatment system

2 FL OZ (59mL)



PROSORIA PSORIASIS TREATMENT

salicylic acid gel

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:71573-102

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	1.77 g in 59 mL

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
Diethylene Glycol Monoethyl Ether (UNII: A1A1I8 X02B)		
Tetrahydrodiferuloylmethane (UNII: 00U0645U03)		
TURMERIC (UNII: 856 YO 1Z64F)		
GAMMA CYCLODEXTRIN (UNII: KZJ0BYZ5VA)		
Oleth-3 Phosphate (UNII: 8Q0Z18J1VL)		
Edetate Disodium Anhydrous (UNII: 8 NLQ36 F6 MM)		
Sodium Hydroxide (UNII: 55X04QC32I)		
Potassium Hydroxide (UNII: WZH3C48M4T)		
Potassium Sorbate (UNII: 1VPU26JZZ4)		
Citric Acid Monohydrate (UNII: 2968PHW8QP)		

Product Characteristics		
Color	WHITE (Off White Beige)	Score
Shape		Size
Flavor		Imprint Code
Contains		

]	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
:	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 FINAL	part358H	11/22/2017	

Labeler - Nuvothera, 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 Nuvothera, Inc.