PROSORIA PSORIASIS TREATMENT- salicylic acid
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 System

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

PRINCIPAL DISPLAY PANEL - Kit Carton

DERMATOLOGIST TESTED

prosoriä

PSORIASIS
treatment system

maximum strength
Salicylic Acid 3% Gel

plus soothing botanicals and vitamins

once daily
2
STEP KIT
once daily

NATIONAL
PSORIASIS
FOUNDATION
RECOGNIZED

- Once Daily
- Relieves: itching, redness & irritated skin
- Rapidly removes scaling & flaking
- Softens & moisturizes

Antioxidant Rich Formula

turmeric root, curcumin shea butter, vitamin E

TREATMENT GEL
2 FL OZ (59mL)

MOISTURIZING OINTMENT
NET WT 2OZ (60g)

PROSORIA PSORIASIS TREATMENT

salicylic acid kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71573-117

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71573-117-03	1 in 1 CARTON	02/18/2022	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	59 mL
Part 2	1 TUBE	60 g

Part 1 of 2

PROSORIA PSORIASIS TREATMENT

salicylic acid gel

Product Information

Item Code (Source)	NDC:71573-102
Route of Administration	TOPICAL

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: A1A1I8X02B)	
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

Color	WHITE (Off White Beige)	Score	

Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

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		

Marketing Information

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

Part 2 of 2

EXFOLIATING AND MOISTURIZING

other skin care preparations ointment

Product Information

Route of Administration	TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**Petrolatum** (UNII: 4T6H12BN9U)	
INGR	**SHEA BUTTER** (UNII: K49155WL9Y)	
INGR	**ALKYL (C12-15) BENZOATE** (UNII: A9EJ3J61HQ)	
INGR	**Salicylic Acid** (UNII: O414PZ4LPZ)	
INGR	**Paraffin** (UNII: I9O0E3H2ZE)	
INGR	**.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		60 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part358H	02/18/2022	

Labeler - Nuvothera, Inc. (080499864)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO		080170933	MANUFACTURE(71573-117)

Establishment

Name	Address	ID/FEI	Business Operations
Global Packaging Systems		964987890	LABEL(71573-117) , PACK(71573-117)

Revised: 3/2022 Nuvothera, Inc.