

PROSORIA SCALP- salicylic acid lotion/shampoo
Nuvothera, Inc.

Prosoriä Scalp Lotion

Drug Facts

Active ingredient

Salicylic acid, 1.8%

Purpose

Antipsoriasis, antiseborrheic

Uses

relieves and helps prevent recurrence of symptoms of psoriasis and/or seborrheic dermatitis 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.

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

Directions

- apply and massage well on affected areas of the scalp once daily or as directed by a doctor. Tip bottle and apply small drops to affected area of the scalp and spread evenly. Let dry and leave on. Shampoo hair when needed.

Other information

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

Inactive ingredients

Water, Petrolatum, Ethoxydiglycol, Oleth-3 Phosphate, Butylene Glycol, Tetrahydrodiferuloylmethane, Polyacrylate Crosspolymer-6, Sodium Hydroxide, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Curcuma Longa (Turmeric) Root Extract, Nigella Sativa Seed Oil, Polyisobutene, Cyclodextrin, Undecylenoyl Glycine, Phenoxyethanol, Capryloyl Glycine, Disodium EDTA, PEG-7 Trimethylolpropane Coconut Ether, Tocopheryl Acetate, Citric Acid.

Questions?

Visit www.prosoria.com or call toll-free 1-833-776-7483 Mon – Fri, 8am – 5pm CT.

Distributed by Nuvothera, Inc.
Fort Worth, Texas 76104

PRINCIPAL DISPLAY PANEL - 74 mL Bottle Label

treats

prosoriä

scalp lotion

1.8% salicylic acid

anti-psoriasis

anti-seborrheic

2.5 FL OZ (74mL)

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Distributed by Nuvothera, Inc.
Fort Worth, Texas 76104 | Made in USA
P55212

PROSORIA SCALP

salicylic acid lotion/shampoo

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71573-116 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ) | Salicylic Acid | 1.33 g in 74 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| Water (UNII: 059QF0K00R) | |
| Diethylene Glycol Monoethyl Ether (UNII: A1A18X02B) | |
| AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9) | |
| Tetrahydrodiferuloylmethane (UNII: 00U0645U03) | |
| TURMERIC (UNII: 856YO1Z64F) | |
| Petrolatum (UNII: 4T6H12BN9U) | |
| Oleth-3 Phosphate (UNII: 8Q0Z18J1VL) | |
| Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM) | |
| Sodium Hydroxide (UNII: 55X04QC32I) | |
| Butylene Glycol (UNII: 3XUS85K0RA) | |
| Nigella Sativa Seed Oil (UNII: CS4U38E731) | |
| Citric Acid Monohydrate (UNII: 2968PHW8QP) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| POLYISOBUTYLENE (1300 MW) (UNII: 241BN7J12Y) | |
| BETADEX (UNII: JV039JZZ3A) | |
| Phenoxyethanol (UNII: HIE492ZZ3T) | |
| HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4) | |
| Undecylenoyl Glycine (UNII: 4D20464K2J) | |
| Capryloyl Glycine (UNII: 8TY5YO42NJ) | |
| PEG-7 Trimethylolpropane Coconut Ether (UNII: MVJ3AD73GG) | |

Product Characteristics

| | | | |
|-----------------|---------------------------------|---------------------|--|
| Color | YELLOW (Off White Light Yellow) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71573-116-09 | 74 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/01/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M032 | 04/01/2022 | |

Labeler - Nuvothena, Inc. (080499864)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|------------------------|
| Swiss-American CDMO | | 080170933 | MANUFACTURE(71573-116) |

Revised: 1/2024

Nuvothera, Inc.