DENOREX EXTRA STRENGTH- salicylic acid shampoo Neoteric Cosmetics, Inc.

Denorex Extra Strength

Drug Facts

Active Ingredients:

Salicylic acid 3%

Purpose

Controls the symptoms of dandruff, seborrheic dermatitis and psoriasis

Uses

- Reduces and helps eliminate scalp itching, flaking and scaling associated with dandruff, seborrheic dermatitis and psoriasis
- Helps prevent recurrence of the symptoms of dandruff, seborrheic dermatitis and psoriasis

Warnings

For external use only.

Ask a doctor before use if you have

a condition that covers a large area of the body.

When using this product

avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if

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

- Shake well
- apply to wet hair
- gently massage into hair and scalp to work up a lather
- rinse thoroughly and repeat

• for best results, use at least twice weekly or as directed by a doctor

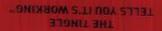
Other information

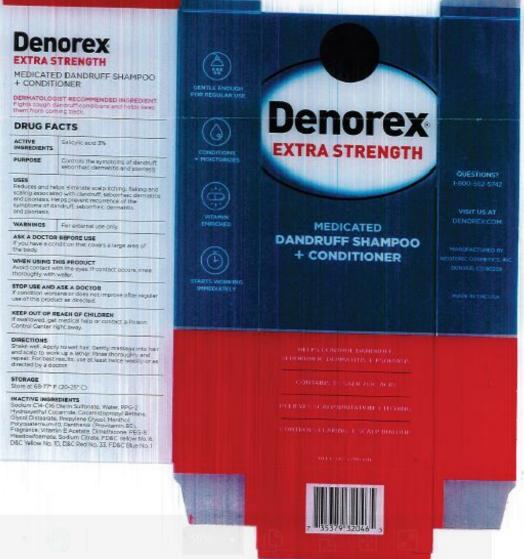
Store at 20°-25° C (68° – 77° F)

Inactive ingredients

cocamidopropyl betaine, D&C Red No. 33, D&C Yellow No. 10, dimethicone PEG-8 meadowfoamate, FD&C Blue No. 1, FD&C Yellow No. 6, fragrance, glycol distearate, menthol, panthenol, polyquaternium-10, PPG-2 hydroxyethyl cocamide, propylene glycol, sodium C14-C16 olefin sulfonate, sodium citrate, vitamin E acetate, water

PRINCIPAL DISPLAY PANEL





Kny.

DENOREX

3 % Salicylic Acid

DANDRUFF Control

SHAMPOO +

CONDITIONER

10 FL OZ (296 mL)

EXTRA STRENGTH

| EXTRA STRENGTH DENDRUEF CONTROL DANDRUEF CONTROL | | ARMATOLOGIST INGREDIENT Programme Noto EXTRA STRENGTH | |
|--|--|---|---|
| Active Ingredients: Purpose: Salicylic acid 3%Controls the symptoms of dandruff, seborrheic dermatitis and psoriasis Uses: • Reduces and helps eliminate scalp itching, flaking and scaling associated with dandruff, seborrheic dermatitis and psoriasis • Helps prevent recurrence of the symptoms of dandruff, seborrheic dermatitis and psoriasis | | Denorex. 3% SALICYLIC ACID DANDRUFF CONTROL | |
| Warnings: For external use only Ask a doctor before use if you have a condition that covers a large area of the body. When using this product avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water. Stop use and ask a doctor if condition worsens or does not improve | | DANDRUFF SHAMPOO + CONDITIONER | |
| 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: • shake well • apply to wet hair • gently massage into hair and scalp to work up a lather • rinse thoroughly and repeat • for best results, use at least twice weekly or a directed by a doctor Other information: Store at 20-25° C (68-77° F) | | Controls Flaking & Scalp Build-Up | |
| Inactive Ingredients: cocamidopropyl betaine, D&C Red No.33, D&C Yellow No.10, dimethicone PEG-8 meadowfoamate, FD&C Blue No.1, FD&C Yellow No.6, fragrance, glycol distearche, menthol, parthenol, polyquaternium-10, PPG-2 hydroxyethyl oocamide, propylene glycol, sodium c14-c16 olefin sulfonate, sodium citrate, vitamin E acetate, water Questions? | Denorex [®] Dandruff Control fights all tough dandruff conditions and is | Helps controls dandruff, seborrheic dermatitis & psoriasis | Denorex [®] Dandruff Control fights a ll tough dandruff conditions and helps |
| 1=800-220-0151 or www.denorexshampoo.com ©2012 Distributed by Ultimark Products [™] Made in USA Plymouth Meeting, PA 19462 DN32046 | gentle enough for everyday use. "The tingle te ll s you it's working." | Relieves scalp irritation, itching & scalp build up Conditioner moisturizes for healthy hair | keep them from coming back. "The tingle tells you it's working." |
| 8 <u>-55093' 32046</u> 3 | | "The Tingle Tells You it's Working." 10FL OZ (296 mL) | |

DENOREX EXTRA STRENGTH salicylic acid shampoo **Product Information Product Type** HUMAN OTC DRUG NDC:62673-058 Item Code (Source) **Route of Administration** TOPICAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength SALICYLIC ACID (UNII: 0414PZ4LPZ) (SALICYLIC ACID - UNII:0414PZ4LPZ) SALICYLIC ACID 0.03 g in 1 mL **Inactive Ingredients Ingredient Name** Strength WATER (UNII: 059QF0KO0R)

SODIUM C14-16 OLEFIN SULFONATE (UNII: 09W3D3YF5U)

| | | L (UNII: 6DC9Q167V3) | | | | | | |
|--------------------------------------|-------------------------------------|---|-------------------------|-----------------------|--|--|--|--|
| | | FE (UNII: 13W7MDN21W) | | | | | | |
| | NTHOL (UNII: L7T | · · | | | | | | |
| со | CAMIDOPROPYL | BETAINE (UNII: 50CF3011KX) | | | | | | |
| PANTHENOL (UNII: WV9CM0067Z) | | | | | | | | |
| .AL | PHATOCOPHER | ROL ACETATE (UNII: 9E8X80D2L0) | | | | | | |
| so | DIUM CITRATE (l | JNII: 1Q73Q2JULR) | | | | | | |
| FDa | &C YELLOW NO. | 6 (UNII: H77VEI93A8) | | | | | | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | | | | | | | | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | | | | | | | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | | | | | | | |
| | | | | | | | | |
| | ckaging | | | | | | | |
| Pa | ickaging Item Code | Package Description | Marketing Start Date | Marketing End Date | | | | |
| Pa # | Item Code | | - | - | | | | |
| Pa # | Item Code NDC:62673-058- 2 10 | Package Description 296 mL in 1 BOTTLE; Type 0: Not a Combination Product | Date | | | | | |
| Pa # | Item Code NDC:62673-058- 2 10 | Package Description 296 mL in 1 BOTTLE; Type 0: Not a Combination | Date | | | | | |
| Pa # | Item Code NDC:62673-058- 2 10 | Package Description 296 mL in 1 BOTTLE; Type 0: Not a Combination Product | Date | - | | | | |

Labeler - Neoteric Cosmetics, Inc. (790615181)

Registrant - Pharma Nobis, LLC (118564114)

| Establishment | | | | | | |
|----------------------|---------|-----------|--|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | |
| Pharma Nobis, LLC | | 118564114 | analysis(62673-058) , manufacture(62673-058) , pack(62673-058) , label(62673-058) | | | |

Revised: 12/2023

Neoteric Cosmetics, Inc.