REVITEALIZE ANTI DANDRUFF - salicylic acid shampoo Camellix, LLC

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.

Drug Facts

Active Ingredients:

Salicylic Acid 1.8%

Purpose:

Help Control of flaking and itching associated with dandruff and scalp psoriasis

LISES

For relief of itching and scalp flaking associated with dandruff, seborrheic dermatitis and psoriasis.

Warnings:

• For external use only.

Keep out of reach of small children. Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water.

If swallowed, get medical help or contact a Poison Control Center immediately. If condition worsens or does not improve after regular use of this product as directed, consult a doctor.

Directions

For best control of dandruff, use every time you shampoo. Wet hair, massage shampoo onto scalp, wait for at least 2 minutes, rinse, repeat if necessary.

For best results use at least twice a week or as directed by a doctor

Inactive Ingredients

Water, Sodium C14-16 Olefin Sulfonate, Cocamidopropyl Betaine, Stach Hydroxypropyltrimonium Chloride, Glycerol Laurate, Green Tea Leaf Extract, SD Alcohol 40 (Alcohol Denatured), Aloe barbadensis Leaf Juice, Polysorbate 20, Glycerin, Panthenol, Retinyl Palmitate, Cholecalciferol, Lavandula Angustifolia (Lavender) Oil, Citrus Aurantium Dulcis (Orange) Peel Oil, Zea Mays (Corn) Oil, Tetrasodium EDTA, DMDM Hydantoin.

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Purpose

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Uses

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Distributed by Camellix, LLC
Center of Innovation for Life Sciences
1120 15th Street, CA 2149 • Augusta, Ga • 30912-7624



ANTI-DANDRUFF SHAMPOO

FOR CONTROL OF IRRITATION, ITCH, AND FLAKES.

FOR ALL HAIR TYPES

No Tar No Sulfur Non Toxic

Developed by: Dr. Stephen Hsu, a professor at Georgia Health Sciences University

NEW PRODUCT WITH GREEN TEA & ALOE VERA

118 ML • 4 FL OZ Sample size, not for sale Made in the USA

REVITEALIZE

www.camellix.com

REVITEALIZE ANTI DANDRUFF

salicylic acid shampoo

| Product Information |
|---------------------|
|---------------------|

Product Type HUMAN OTC DRUG Item Code (Source) NDC:54866-000

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------------------------|-------------------|---------------|
| Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ) | Salicylic Acid | 18 mg in 1 mL |

| Inactive Ingredients | |
|---------------------------------------------------|----------|
| Ingredient Name | Strength |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U) | |
| COCAMIDO PRO PYL BETAINE (UNII: 50CF3011KX) | |
| GLYCERYL LAURATE (UNII: Y98611C087) | |

| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
|------------------------------------------|--|
| ALCOHOL (UNII: 3K9958V90M) | |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PANTHENOL (UNII: WV9CM0O67Z) | |
| VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC) | |
| CHOLECALCIFEROL (UNII: 1C6 V77QF41) | |
| LAVENDER OIL (UNII: ZBP1YXW0H8) | |
| ORANGE OIL (UNII: AKN3KSD11B) | |
| CORN OIL (UNII: 8470G57WFM) | |
| EDETATE SO DIUM (UNII: MP1J8420LU) | |
| DMDM HYDANTO IN (UNII: BYR0546 TOW) | |
| | |

| P | ackaging | | | |
|---|------------------|-----------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:54866-000-02 | 118 mL in 1 BOTTLE, PLASTIC | | |

| Marketing Information | | | |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part358H | 12/0 1/20 11 | |
| | | | |

Labeler - Camellix, LLC (968429386)

Registrant - RAANI CORPORATION (067084681)

| Establishment | | | | |
|-------------------|---------|-----------|---------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| RAANI CORPORATION | | 067084681 | manufacture | |

Revised: 12/2011 Camellix, LLC