

**AFFIRM CARE SCALP THERAPY ANTI-DANDRUFF EXFOLIATING MASQUE-  
pyrithione zinc lotion  
Avlon Industries, Inc.**

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**AffirmCare Scalp Therapy - Anti-Dandruff Exfoliating Masque**

**Active Ingredient**

Zinc Pyrithione 1%

**Purpose**

Anti-Dandruff, Anti-Seborrheic Dermatitis

**Uses**

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

**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 eyes. If contact occurs, rinse eyes thoroughly with water.

**Stop use and ask a doctor if**

- Condition worsens or does not improve with regular use.

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

**Directions**

- For best results, use at least twice a week, or as directed by a doctor.
- Shake well before use.
- Apply after rinsing Scalp Therapy Hydrating Anti-Dandruff Shampoo by gently massaging into hair and scalp. Rinse well.

**Inactive Ingredient**

Aqua/Water/Eau, Aloe Barbadensis Leaf Juice, Betaine, Cetearyl Alcohol, Cocos

Nucifera (Coconut) Oil, Cetyl Alcohol, Juglans Regia (Walnut) Shell Powder, Glycerin, Behentrimonium Chloride, Stearamidopropyl Dimethylamine, Phytosterols, Butyrospermum Parkii (Shea) Butter, Mangifera Indica (Mango) Seed Butter, Melia Azadirachta Seed Oil, Origanum Vulgare Leaf Extract, Nigella Sativa Seed Oil, Linum Usitatissimum (Linseed) Seed Extract, Camellia Sinensis Leaf Extract, Menthol, Keratin, Hydrolyzed Keratin, Piroctone Olamine, Panthenol, Polyquaternium-37, PPG-1 Trideceth-6, Phenoxyethanol, Caprylyl Glycol, Caprylic Acid, Fragrance/Parfum, Citric Acid, Isostearyl Ethylimidazolium Ethosulfate, Polyacrylamide, Propylene Glycol Dicaprylate/Dicaprate, Dipropylene Glycol, Amyl Cinnamal, Benzyl Benzoate, Limonene, Hexyl Cinnamal.

## Questions or comments? 1-800-332-8566

AffirmCare Scalp Therapy  
Anti-Dandruff Exfoliating Masque (8 oz & 32 oz)

Product NDC# 63766-302



|  |  |   |  |   |  |
|--|--|---|--|---|--|
| <b>Drug Facts</b><br><b>Active Ingredient</b><br>Zinc Pyrithione 1%.....<br><b>Purpose</b><br>Anti-Dandruff,<br>Anti-Seborrheic Dermatitis |  | <b>Drug Facts (Continued)</b><br><b>When using this product</b><br>■ Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.<br><b>Stop use and ask a doctor if</b><br>■ Condition worsens or does not improve with regular use.<br><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away. |  | <b>Inactive Ingredients</b><br>Aqua/Water/Eau, Aloe Barbadensis Leaf Juice, Betaine, Cetearyl Alcohol, Cocos Nucifera (Coconut) Oil, Cetyl Alcohol, Juglans Regia (Walnut) Shell Powder, Glycerin, Behentrimonium Chloride, Stearamidopropyl Dimethylamine, Phytosterols, Butyrospermum Parkii (Shea) Butter, Mangifera Indica (Mango) Seed Butter, Melia Azadirachta Seed Oil, Origanum Vulgare Leaf Extract, Nigella Sativa Seed Oil, Linum Usitatissimum (Linseed) Seed Extract, Camellia Sinensis Leaf Extract, Menthol, Keratin, Hydrolyzed Keratin, Piroctone Olamine, Panthenol, Polyquaternium-37, PPG-1 Trideceth-6, Phenoxyethanol, Caprylyl Glycol, Caprylic Acid, Fragrance/Parfum, Citric Acid, Isostearyl Ethylimidazolium Ethosulfate, Polyacrylamide, Propylene Glycol Dicaprylate/Dicaprate, Dipropylene Glycol, Amyl Cinnamal, Benzyl Benzoate, Limonene, Hexyl Cinnamal. |  |
| <b>Uses</b> for the relief of scalp flaking, itching and irritation associated with dandruff and seborrheic dermatitis.                    |  | <b>Directions</b><br>■ For best results, use at least twice a week, or as directed by a doctor.<br>■ Apply after rinsing Scalp Therapy Hydrating Anti-Dandruff Shampoo by gently massaging into hair and scalp. Rinse well.   |  | ©2018. Researched and Formulated by Avlon Industries, Inc.<br>Melrose Park, IL 60160 USA<br>Made in USA www.avlon.com   |  |
| <b>Warnings</b><br>■ For external use only<br>Ask a doctor before use if you have a condition that covers a large area of the body.        |  | PEEL BACK TO SEE DRUG FACTS   |  | SATISFACTION GUARANTEED<br>Professional Formula   |  |
| Questions or comments? 1-800-332-8566  |  |   |  |   |  |

# AFFIRM CARE SCALP THERAPY ANTI-DANDRUFF EXFOLIATING MASQUE

pyrithione zinc lotion

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:63766-302 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength     |
|---|-------------------|--------------|
| <b>PYRITHIONE ZINC</b> (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5) | PYRITHIONE ZINC   | 10 mg in 1 g |

## Inactive Ingredients

| Ingredient Name                          | Strength |
|--|----------|
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X) |          |

|   |
|---|
| <b>COCONUT OIL</b> (UNII: Q9L0073W7L)                             |
| <b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)                          |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)                           |
| <b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)                     |
| <b>BETAINE</b> (UNII: 3SCV180C9W)                                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                |
| <b>MANGIFERA INDICA SEED BUTTER</b> (UNII: 4OXD9M35X2)            |
| <b>BEHENTRIMONIUM CHLORIDE</b> (UNII: X7GNG3S47T)                 |
| <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)                 |
| <b>AZADIRACHTA INDICA SEED OIL</b> (UNII: 4DKJ9B3K2T)             |
| <b>POLYQUATERNIUM-37 (10000 MPA.S)</b> (UNII: 41QWS48DFN)         |
| <b>LINSEED OIL</b> (UNII: 84XB4DV00W)                             |
| <b>PIROCTONE OLAMINE</b> (UNII: A4V5C6R9FB)                       |
| <b>CAPRYLIC ACID</b> (UNII: OBL58JN025)                           |
| <b>NIGELLA SATIVA SEED OIL</b> (UNII: CS4U38E731)                 |
| <b>PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: O4446S9CRA)  |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                          |
| <b>POLYACRYLAMIDE (10000 MW)</b> (UNII: E2KR9C9V2I)               |
| <b>MENTHOL</b> (UNII: L7T10EIP3A)                                 |
| <b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)                      |
| <b>PPG-1 TRIDECETH-6</b> (UNII: 1K7417JX6Q)                       |
| <b>OREGANO</b> (UNII: 0E5AT8T16U)                                 |
| <b>BENZYL BENZOATE</b> (UNII: N863NB338G)                         |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                             |
| <b>.ALPHA.-HEXYLCINNAMALDEHYDE</b> (UNII: 7X6O37OK2I)             |
| <b>.ALPHA.-AMLYCINNAMALDEHYDE</b> (UNII: WC51CA3418)              |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                         |
| <b>WATER</b> (UNII: 059QF0KO0R)                                   |
| <b>AMINO ACIDS, HAIR KERATIN</b> (UNII: G46579QK1M)               |
| <b>HYDROLYZED SHEEP WOOL KERATIN (2000 MW)</b> (UNII: NZR037QF7Z) |
| <b>STEARAMIDOPROPYL DIMETHYLAMINE</b> (UNII: K7VEI00UFR)          |
| <b>ISOSTEARYL ETHYLIMIDAZOLIUM ETHOSULFATE</b> (UNII: MZE1E3A2ZS) |
| <b>JUGLANS REGIA WHOLE</b> (UNII: 87EJ76IO83)                     |
| <b>PANTHENOL</b> (UNII: WW9CM0O67Z)                               |
| <b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)                          |
| <b>.BETA.-SITOSTEROL</b> (UNII: S347WMO6M4)                       |

### Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63766-302-01 | 227 g in 1 JAR; Type 0: Not a Combination Product | 09/13/2018           |                    |
| 2 | NDC:63766-302-02 | 907 g in 1 JAR; Type 0: Not a Combination Product | 09/13/2018           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

OTC Monograph Drug M032

09/13/2018

**Labeler** - Avlon Industries, Inc. (121278626)

**Establishment**

| Name                 | Address | ID/FEI    | Business Operations    |
|----------------------|---------|-----------|------------------------|
| Avlon Industries Inc |         | 121278626 | manufacture(63766-302) |

Revised: 2/2024

Avlon Industries, Inc.