

# **AFFIRM CARE SCALP THERAPY HYDRATING ANTI-DANDRUFF- pyrithione zinc shampoo**

**Avlon Industries, Inc.**

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**AffirmCare Scalp Therapy - Hydrating Anti-Dandruff Shampoo**

## **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 by massaging onto wet hair and scalp.
- Rinse and repeat. Follow with Scalp Therapy Hydrating Anti-Dandruff Conditioner.

## **Inactive Ingredient**

Aqua/Water/Eau, Aloe Barbadensis Leaf Juice, Disodium

Laureth Sulfosuccinate, Betaine, Cocamidopropyl Betaine, Cocamide MIPA, Sodium Cocoyl Isethionate, Cetyl Alcohol, Melia Azadirachta Seed Oil, Origanum Vulgare Leaf Extract, Linum Usitatissimum (Linseed) Seed Extract, Camellia Sinensis Leaf Extract, Menthol, Keratin, Hydrolyzed Keratin, Glycol Stearate, Glycerin, Piroctone Olamine, Phenoxyethanol, Caprylyl Glycol, Caprylic Acid, Fragrance/Parfum, Tetrasodium EDTA, Cetareth-60 Myristyl Glycol, Quaternium-80, Polyquaternium-10, Propanediol, Benzyl Benzoate, Limonene, Hexyl Cinnamal.

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

AffirmCare Scalp Therapy

Hydrating Anti-Dandruff Shampoo (8 oz & 32 oz)

Product NDC# 63766-300

**Drug Facts**

Active Ingredient	Purpose
Zinc Pyrithione 1%	Anti-Dandruff, Anti-Seborrheic Dermatitis

**Use** for the relief of scalp flaking, itching and irritation associated with dandruff and seborrheic dermatitis.

**Warnings**  
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 ■ Shake before use.  
 ■ Apply by massaging onto wet hair and scalp.  
 ■ Rinse and repeat. Follow with Scalp Therapy Hydrating Anti-Dandruff Conditioner.

**Inactive Ingredients**  
 Aqua/Water/Eau, Aloe Barbadensis Leaf Juice, Disodium Laureth Sulfosuccinate, Betaine, Cocamidopropyl Betaine, Cocamide MIPA, Sodium Cocoyl Isethionate, Cetyl Alcohol, Melia Azadirachta Seed Oil, Origanum Vulgare Leaf Extract, Linum Usitatissimum (Linseed) Seed Extract, Camellia Sinensis Leaf Extract, Menthol, Keratin, Hydrolyzed Keratin, Glycol Stearate, Glycerin, Piroctone Olamine, Phenoxyethanol, Caprylyl Glycol, Caprylic Acid, Fragrance/Parfum, Tetrasodium EDTA, Cetareth-60 Myristyl Glycol, Quaternium-80, Polyquaternium-10, Propanediol, Benzyl Benzoate, Limonene, Hexyl Cinnamal.

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**AVLON**  
THE SCIENCE of HAIRCARE®

**AFFIRM CARE**  
Scalp Therapy

**HYDRATING ANTI-DANDRUFF SHAMPOO**  
With Neem and Oregano

Scalp Therapy Hydrating Anti-Dandruff Shampoo is a conditioning shampoo with zinc pyrithione, which helps eliminate dandruff flakes and provides relief from dry, itchy and irritated scalp. Leaves hair easy to detangle. Regular use controls recurrence of dry and itchy scalp conditions.

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SATISFACTION GUARANTEED  
Professional Formula

SLS FREE  
PHTHALATE FREE

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**AFFIRM CARE SCALP THERAPY HYDRATING ANTI-DANDRUFF**

pyrithione zinc shampoo

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63766-300
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	
<b>BENZYL BENZOATE</b> (UNII: N863NB338G)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM COCOYL ISETHIONATE</b> (UNII: 518XTE8493)	
<b>LINSEED OIL</b> (UNII: 84XB4DV00W)	
<b>GLYCOL STEARATE</b> (UNII: 0324G66D0E)	
<b>POLYQUATERNIUM-10 (125 MPA.S AT 2%)</b> (UNII: L45WU8S981)	
<b>PIROCTONE OLAMINE</b> (UNII: A4V5C6R9FB)	
<b>AZADIRACHTA INDICA SEED OIL</b> (UNII: 4DKJ9B3K2T)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>OREGANO</b> (UNII: 0E5AT8T16U)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>BETAINE</b> (UNII: 3SCV180C9W)	
<b>DISODIUM LAURETH SULFOSUCCINATE</b> (UNII: D6DH1DTN7E)	
<b>COCO MONOISOPROPANOLAMIDE</b> (UNII: 21X4Y0VTB1)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>CETEARETH-60 MYRISTYL GLYCOL</b> (UNII: 4O832Z0Y6W)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>.ALPHA.-HEXYLCINNAMALDEHYDE</b> (UNII: 7X6O37OK2I)	
<b>CAPRYLIC ACID</b> (UNII: OBL58JN025)	
<b>HYDROLYZED SHEEP WOOL KERATIN (2000 MW)</b> (UNII: NZR037QF7Z)	
<b>AMINO ACIDS, HAIR KERATIN</b> (UNII: G46579QK1M)	
<b>2-(CYCLOHEXYLAMINO)ETHANESULFONIC ACID</b> (UNII: 71X53V3RZ1)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:63766-300-01	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	09/13/2018
2	NDC:63766-300-02	950 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
3	NDC:63766-300-72	240 mL in 1 TUBE; Type 0: Not a Combination Product	09/12/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M032	09/12/2018	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Avlon Industries Inc		121278626	manufacture(63766-300)

Revised: 2/2024

Avlon Industries, Inc.