

AFFIRM CARE SCALP THERAPY HYDRATING ANTI-DANDRUFF- pyrrithione zinc shampoo

Avlon Industries, Inc.

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.

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

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Avlon THE SCIENCE of HAIRCARE®

AFFIRM CARE
Scalp Therapy

HYDRATING ANTI-DANDRUFF SHAMPOO
With Neem and Oregano

SLS FREE
PHTHALATE FREE

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SATISFACTION GUARANTEED
Professional Formula

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AFFIRM CARE SCALP THERAPY HYDRATING ANTI-DANDRUFF

pyrithione zinc shampoo

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL BENZOATE (UNII: N863NB338G)	
WATER (UNII: 059QF0K00R)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
LINSEED OIL (UNII: 84XB4DV00W)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
POLYQUATERNIUM-10 (125 MPA.S AT 2 %) (UNII: L45WU8S981)	
PIROCTONE OLAMINE (UNII: A4V5C6R9FB)	
AZADIRACHTA INDICA SEED OIL (UNII: 4DKJ9B3K2T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPANEDIOL (UNII: 5965N8W85T)	
OREGANO (UNII: 0E5AT8T16U)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
BETAINE (UNII: 3SCV180C9W)	
DISODIUM LAURETH SULFO SUCCINATE (UNII: D6DH1DTN7E)	
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
MENTHOL (UNII: L7T10EIP3A)	
CETEARETH-60 MYRISTYL GLYCOL (UNII: 4O832ZOY6W)	
EDETATE SODIUM (UNII: MP1J8420LU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAPRYLIC ACID (UNII: OBL58JN025)	
HYDROLYZED SHEEP WOOL KERATIN (2000 MW) (UNII: NZR037QF7Z)	
AMINO ACIDS, HAIR KERATIN (UNII: G46579QK1M)	
2-(CYCLOHEXYLAMINO)ETHANESULFONIC ACID (UNII: 71X53V3RZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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 final	part358H	09/12/2018	

Labeler - Avlon Industries, Inc. (121278626)

Establishment

Name	Address	ID/FEI	Business Operations

Revised: 11/2019

Avlon Industries, Inc.