

**KERACARE DRY AND ITCHY SCALP ANTI-DANDRUFF- pyrithione zinc lotion/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.

KeraCare Dry and Itchy Scalp Anti-Dandruff Moisturizing Conditioner

Active Ingredient

Pyrithione Zinc 1%

Purpose

Anti-Dandruff, Anti-Seborrheic Dermatitis

Use 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

- seborrheic dermatitis that covers large areas of your body.

When using this product

- Avoid getting into eyes. In event of contact, rinse eyes thoroughly with water.
- Use caution in exposing skin to sunlight after applying this product. It may increase your tendency to sunburn for up to 24 hours after application.

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

Distribute throughout hair after shampooing with KeraCare® Dry & Itchy Scalp Anti-Dandruff Moisturizing Shampoo. Cover hair with plastic cap. Leave on a few minutes and rinse thoroughly.

Inactive Ingredients

Aqua/Water/Eau, Cocos Nucifera (Coconut) Oil, Betaine, Aloe Barbadensis Leaf Juice, Cetearyl Alcohol, Glycerin, Stearamidopropyl Dimethylamine, Linum Usitatissimum

(Linseed) Seed Extract, Quaternium-80, Piroctone Olamine, Menthol, Polyquaternium-37, Propylene Glycol Dicaprylate/Dicaprate, PPG-1 Trideceth-6, Fragrance/Parfum, Polyquaternium-10, Dipropylene Glycol, Propanediol, Caprylyl Glycol, Phenoxyethanol, Citric Acid, Polyacrylamide, Benzyl Salicylate, Hexyl Cinnamal, Linalool.

KeraCare Dry and Itchy Scalp Anti-Dandruff Moisturizing Conditioner

Product NDC 63766-003



KERACARE®



Professional Formula
Satisfaction Guaranteed

DRY & ITCHY
SCALP

2

Anti-Dandruff
Moisturizing
Conditioner

CONDITION

W

pH 4.0



The technologically-advanced KeraCare® Dry & Itchy Scalp Anti-Dandruff Moisturizing Conditioner effectively combats a dry and itchy scalp as it moisturizes and conditions hair. It: • Actively relieves itching • Soothes scalp • Rehydrates and rebuilds damaged fibers • Detangles hair • Regular use helps prevent dryness, itching and flaking.

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

■ For external use only

Ask a doctor before use if you have

■ seborrheic dermatitis that covers large areas of your body.

When using this product

- Avoid getting into eyes. In event of contact, rinse eyes thoroughly with water.
- Use caution in exposing skin to sunlight after applying this product. It may increase your tendency to sunburn for up to 24 hours after application.

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

■ Distribute throughout hair after shampooing with KeraCare® Dry & Itchy Scalp Anti-Dandruff Moisturizing Shampoo. Cover hair with plastic cap. Leave on a few minutes and rinse thoroughly.

Inactive Ingredients

Aqua/Water/Eau, Cocos Nucifera (Coconut) Oil, Betaine, Aloe Barbadensis Leaf Juice, Cetearyl Alcohol, Glycerin, Stearamidopropyl Dimethylamine, Linum Usitatissimum (Linseed) Seed Extract, Quaternium-80, Piroctone Olamine, Menthol, Polyquaternium-37, Propylene Glycol Dicaprylate/Dicaprate, PPG-1 Trideceth-6, Fragrance/Parfum, Polyquaternium-10, Dipropylene Glycol, Propanediol, Caprylyl Glycol, Phenoxyethanol, Citric Acid, Polyacrylamide, Benzyl Salicylate, Hexyl Cinnamal, Linalool.

©2019 Researched and Formulated by Avlon Industries, Inc.
1999 N. 15th Ave. Melrose Park, IL 60160 USA

Unit 2 Navigation Point, Tipton DY4 OPY UK • Weena Zuid 130, 3012 NC Rotterdam NL
Made in USA / Fabriqué aux États-Unis • www.Avlon.com

KERACARE DRY AND ITCHY SCALP ANTI-DANDRUFF

pyrithione zinc lotion/shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63766-003
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
COCONUT OIL (UNII: Q9L0O73W7L)	
BETAINE (UNII: 3SCV180C9W)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PIROCTONE OLAMINE (UNII: A4V5C6R9FB)	
PPG-1 TRIDECETH-6 (UNII: 1K7417JX6Q)	
PROPANEDIOL (UNII: 5965N8W85T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARAMIDOPROPYL DIMETHYLAMINE (UNII: K7VEI00UFR)	
MENTHOL (UNII: L7T10EIP3A)	
PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
FLAX SEED (UNII: 4110YT348C)	
2-(CYCLOHEXYLAMINO)ETHANESULFONIC ACID (UNII: 71X53V3RZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63766-003-01	240 mL in 1 TUBE; Type 0: Not a Combination Product	06/18/2009	
2	NDC:63766-003-02	950 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2009	
3	NDC:63766-003-03	15 mL in 1 POUCH; Type 0: Not a Combination Product	06/18/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	06/18/2009	

Labeler - Avlon Industries, Inc. (121278626)

Establishment

Name	Address	ID/FEI	Business Operations
Avlon Industries, Inc.		121278626	manufacture(63766-003)