VITALE SENSITIVE SCALP DAILY SCALP HEALER- pyrithione zinc cream New Life Products, 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.

Drug Facts

Active Ingredient

Pyrithione Zinc 0.25%

Purpose

Anti-Dandruff

Use

Controls the symptoms of dandruff

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 adoctor if condition worsens or dowes not improve after regular use of this product as directed.

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

Directions:

For best results apply to affected areas one to four times daily or as directed by a doctor. Spread a small amount in the palms of your hands and apply evenly to the scalp and entire head of hair. Style as desired.

Inactive ingredients

Water (Aqua), Glycerin, Propylene Glycol, Mineral Oil (Paraffinum Liquidum), Lanolin, Acetamide MEA, Cetyl Alcohol, Cetearyl Alcohol, Polysorbate 60, Beeswax, Triticum Vulgare (Wheat) Germ Oil, Olea Europaea (Olive) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Menthol, Camphor, Eucalyptus Globulus Leaf Oil, Aloe Barbadensis Leaf Juice, Dimethicone, Tocopherol Acetate (Vitamin E), Retinyl Palmitate (Vitamin A), Stearalkonium Chloride, Polyquaternium-11, Biotin, Rosmarinus Officinalis (Rosemary) Leaf Extract, Equisetum Arvense Extract, Humulus Lupulus (Hops) Extract, Citrus Medica Limonum, (Lemon) Peel Extract, Sodium Borate, DMDM Hydantoin, Methylparaben, Propylparaben, Fragrance, (Parfum)

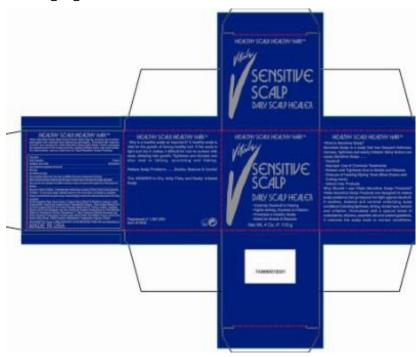
AFAM CONCEPT, INC. Chicago, IL 60629

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Registered # 1,387,930

Packaging





VITALE SENSITIVE SCALP DAILY SCALP HEALER

pyrithione zinc cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49681-001	

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	250 mg in 100 g	

Inactive Ingredients	
Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)	
MINERAL OIL (UNII: T5L8T28FGP)	
LANOLIN (UNII: 7EV65EAW6H)	
ACETIC MONOETHANOLAMIDE (UNII: A9 O 0 8 18 TWD)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
WHEAT GERM OIL (UNII: 14C97E680P)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
JOJOBA OIL (UNII: 724GKU717M)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
STEARALKONIUM CHLORIDE (UNII: 0 O U O 26 BB88)	
POLYQUATERNIUM-11 (1000000 MW) (UNII: 0B44BS5IJS)	
BIOTIN (UNII: 6SO6U10H04)	
ROSEMARY (UNII: IJ67X351P9)	
EQ UISETUM ARVENSE BRANCH (UNII: 1L0 VKZ185E)	
HOPS (UNII: 01G73H6H83)	
LEMON PEEL (UNII: 72O054U628)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
DMDM HYDANTO IN (UNII: BYR0546TOW)	
METHYLPARABEN (UNII: A218 C7H19 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics				
Color	white (Off white)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

	P	ackaging			
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:49681-001-01	114 g in 1 JAR; Type 0: Not a Combination Product	11/01/2009	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part358H	11/01/2009		

Labeler - New Life Products, Inc. (117815140)

Registrant - New Life Products, Inc. (117815140)

Establishment				
Name	Address	ID/FEI	Business Operations	
New Life Products, Inc.		1178 15140	manufacture (49681-001)	

Revised: 1/2021 New Life Products, Inc.