

**VITALE SENSITIVE SCALP DAILY SCALP HEALER- pyrrithione 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.*

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**Drug Facts**

**Active Ingredient**

Pyrrithione 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 a doctor if condition worsens or does 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 Barbadosensis 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)

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Registered # 1,387,930

## Packaging



## VITALE SENSITIVE SCALP DAILY SCALP HEALER

pyrithione zinc cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49681-001
<b>Route of Administration</b>	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: 6DC9Q167V3)
MINERAL OIL (UNII: T5L8T28FGP)
LANOLIN (UNII: 7EV65EAW6H)
ACETIC MONOETHANOLAMIDE (UNII: A9O0818TWD)
CETYL ALCOHOL (UNII: 936JST6JCN)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
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)
DIMETHICONE (UNII: 92RU3N3Y1O)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
STEARALKONIUM CHLORIDE (UNII: 0OUO26BB88)
POLYQUATERNIUM-11 (1000000 MW) (UNII: 0B44BS5IJS)
BIOTIN (UNII: 6SO6U10H04)
ROSEMARY (UNII: IJ67X351P9)
EQUISETUM ARVENSE BRANCH (UNII: 1L0VKZ185E)
HOPS (UNII: 01G73H6H83)
LEMON PEEL (UNII: 72O054U628)
SODIUM BORATE (UNII: 91MBZ8H3QO)
DMDM HYDANTOIN (UNII: BYR0546TOW)
METHYLPARABEN (UNII: A2I8C7HI9T)
PROPYLPARABEN (UNII: Z8IX2SC1OH)

### Product Characteristics

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

### Packaging

#	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	

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**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(4968 1-00 1)

Revised: 1/2021

New Life Products, Inc.