# DANDRUFF- pyrithione zinc shampoo Ecocare

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 Ingredients**

# **Purpose**

Zinc Pyrithione 0.95%......Anti-Dandruff

# Purpose

**Uses:** Helps prevent recurrence of flaking and itching associated with dandruff.

# Warnings

#### FOR EXTERNAL USE ONLY

#### When using this product

Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water.

#### Stop use and ask a doctor if

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

Keep out of reach of children.

# Dosage and Administration

- Shake well.
- Wet hair thoroughly.
- Massage a liberal quantity of shampoo evenly onto the scalp and rinse. Repeat and allow to remain on the scalp for a few minutes.
- Rinse throroughly.
- For best results use at least twice a week or as directed by a doctor.

#### Other Information

For external use only

#### **Inactive Ingredients**

Aqua (Deionized Water), Decyl Glucoside, Lauryl Glucoside, Coco Glucoside, Hydrolyzed Soy Protein, Guar Hydroxypropyltrimonium Chloride, Hydrolyzed Keratin, Tocopherol, Pantothenic Acid, Saccharomyces/Selenium Ferment, Calcium Chloride, Copper Gluconate, Potassium Chloride, Managanese Gluconate, Magnesium Gluconate, Zinc Gluconate, Sodium Chloride, Olea Europaea Fruit Oil, Myrtus Comunis Oil, Lavandula Angustifolia Oil, Thymus Vulgaris Oil, Rosmarinus Officinalis

Leaf Oil, Prunus Armeniaca Kernal Oil, Eugenia Caryophyllus Flower Oil, Oryza Sativa Powder, Tapioca Starch, Carica Papayan Fruit, Yeast Extract, Rosmarinus Officinalis Leaf Powder, Salvia Officinalis Leaf Extract, Sucrose, Phenethyl Alcohol, Caprylyl Glycol, Citric Acid, Tetrasodium EDTA, Essential Oils Blend

#### **Indications**

Helps prevent recurrance of flaking and itching associated with dandruff.

#### Do Not Use

• Condition worsens or does not improve after regular use of this product as directed.

# Ask a doctor

• Condition worsens or does not improve after regular use of this product as directed.

#### **Directions**

- Shake well.
- Wet hair thoroughly.
- Massage a liberal quantity of shampoo evenly onto the scalp and rinse. Repeat and allow to remain on the scalp for a few minutes.
- Rinse thoroughly.
- For best results use at least twice a week or as directed by a doctor.

# image of label



#### **DANDRUFF SHAMPOO**

contains the active ingredient that is treating and preventing itching, flaking, and scaling of the scalp caused by dandruff or seborrhea.

Gently cleanses and prevents dryness

H.N.C. (Hair Nutrition Complex) nourishes scalp and hair. Restores a healthy condition.









Made in U.S.A. Dist. by Ecocare USA Inc. Fort Lee, NJ 07024

www.ecocare.com



# DANDRUFF SHAMP00

Hair & Scalp

PARABEN FREE SULFATE FREE **DEA/MEA FREE** WHEAT FREE NO PHTHALATES

10 fl. oz. e 300 ml

#### **Drug Facts**

Active Ingredient

Purpose Anti-Dandruff

Zinc Pyrithione 1%

 Helps prevent recurrence of flaking and itching associated with dandruff.

#### Warnings

For external use only.

#### When using this product

 Avoid contact with the 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

Consult a physician prior to use in children under 2 years of age. In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

#### **Directions for use**

- Shake well
- Wet hair thoroughly.
- Massage a liberal quantity of shampoo evenly onto the scalp and rinse. Repeat and allow to remain on the scalp for a few minutes.
- Rinse thoroughly.
- For best results use at least twice a week or as directed by a doctor.

#### **Inactive Ingredients**

Aqua (Deionized Water), Disodium Laureth Sulfosuccinate, Cocamidopropyl Betaine, Decyl Glucoside, Cocamidopropyl PG-Dimonium Chloride, Acrylates Copolymer, Guar Hydroxypropyltrimonium Chloride, Polysorbate 80, Glycine Soja (Soybean) Oil, Cocos Nucifera (Coconut) Oil, Olea Europaea (Olive) Fruit Oil, Propylene Glycol Dibenzoate, Hydrolyzed Thymus Vulgaris (Thyme) Oil, Rosmarinus Officinalis (Rosemary) Leaf Oil, Prunus Armeniaca (Apricot) Kernel Oil, Eugenia Caryophyllus (Clove) Flower Oil Saccharomyces/Selenium Ferment, Calcium Chloride, Copper Gluconate, Potassium Chloride, Sodium Chloride, Magnesium Gluconate, Zinc Gluconate, Pantothenic Acid, Oryza Sativa (Rice) Leaf Powder, Sucrose, Tocopherol, Citrus Aurantium Dulcis (Orange) Peel Oil, Beta-Carotene, Carthamus Tinctorius (Safflower) Flower Powder, Caprylyl Glycol, Phenethyl Alcohol, Climbazole, Piroctone Olamine,

#### **Questions or Comments?**

Call: 201-676-2471 Email: info@ecocare.com

#### **DANDRUFF**

pyrithione zinc shampoo

#### **Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:46607-112

**Route of Administration** 

**TOPICAL** 

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	10.0 mg in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
DISO DIUM 1-(LAURETH-2) SULFO SUCCINATE (UNII: 0 A13NT4QUI)	
COCAMIDO PRO PYL BETAINE (UNII: 50CF3O11KX)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
COCAMIDO PRO PYL PG-DIMO NIUM CHLO RIDE (UNII: 205Z54J075)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
AMINO ACIDS, HAIR KERATIN (UNII: G46579 QK1M)	
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)	
TOCOPHEROL (UNII: R0ZB2556P8)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PANTO THENIC ACID (UNII: 19 F5HK2737)	
SO YBEAN OIL (UNII: 241ATL177A)	
CALCIUM CHLORIDE (UNII: M4I0 D6 VV5M)	
COCONUT OIL (UNII: Q9L0O73W7L)	
COPPER GLUCONATE (UNII: RV823G6G67)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL DIBENZOATE (UNII: EQY32Z1AN4)	
PO TASSIUM CHLO RIDE (UNII: 660 YQ 98 I10)	
SUPERO XIDE DISMUTASE (SACCHARO MYCES CEREVISIAE) (UNII: W2T4YRA9 AD)	
MANGANESE GLUCONATE (UNII: 9 YY2F980 SV)	
MAGNESIUM GLUCONATE (UNII: T42NAD2KHC)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	
SO DIUM CHLO RIDE (UNII: 451W47IQ8X)	
OLEA EUROPAEA FRUIT VOLATILE OIL (UNII: 8 E7358 CX1J)	
MYRTUS COMMUNIS LEAF (UNII: U20 N87188F)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19 AH1RAF4M)	
ORANGE PEEL (UNII: TI9T76 XD44)	
THYMUS VULGARIS LEAF (UNII: GRX3499643)	
BETA CAROTENE (UNII: 01YAE03M7J)	
ROSMARINUS OFFICINALIS FLOWERING TOP OIL (UNII: OXN0D3N28L)	
SAFFLOWER (UNII: 4VBL71TY4Y)	
PRUNUS ARMENIACA LEAF (UNII: 0 X5YG5R83N)	
4-METHYLPHENETHYL ALCOHOL (UNII: GG36R9LNV8)	
CLOVE LEAF OIL (UNII: VCA5491KVF)	
ORYZA SATIVA WHOLE (UNII: 84IVV0906Z)	
CLIMBAZOLE (UNII: 9N42CW7I54)	
STARCH, TAPIO CA (UNII: 24SC3U704I)	
PIROCTONE OLAMINE (UNII: A4V5C6R9FB)	
CARICA PAPAYA WHO LE (UNII: S0U63B0Q51)	
DISO DIUM EDTA-CO PPER (UNII: 6 V475AX06U)	
YEAST (UNII: 3NY3SM6B8U)	

ROSMARINUS OFFICINALIS FLOWER (UNII: NR1A27F29O)	
SALVIA OFFICINALIS FLOWERING TOP (UNII: 48 JCS 720 FN)	
SUCROSE (UNII: C151H8 M554)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
CITRIC ACID ACETATE (UNII: DSO 12WL7AU)	
TRIMETHYLENEDIAMINETETRAACETIC ACID (UNII: 3F6 O A9 4EER)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:46607-112- 01	300 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/29/2017			
2	NDC:46607-112- 02	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/29/2017			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part358H	12/29/2017			

# **Labeler -** Ecocare (785638821)

Revised: 4/2020 Ecocare