

TREATMENT- zinc pyrithione cream
Zero Flakes Given, LLC.

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.

Treatment Serum

Zinc Pyrithione 0.125%

Anti-Dandruff

For external use only.

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

If condition worsens or does not improve after regular use of this product as directed, consult a doctor.

Keep out of reach of children. If swallowed, call a poison control center or get medical help right away.

Do not use on children under 2 years of age, unless directed by a doctor.

For the relief of symptoms from scalp itch, irritation, flaking and redness associated with dandruff.

Apply to affected areas 1 to 4 times daily or as directed by a doctor.

Apply liberally to damp or dry scalp, and gently massage with fingertips.

Do not rinse off.

1-877-No-Flake (1-877-663-5253)

Aqua (Water, Eau), Aloe Barbadensis Leaf Juice, Propanediol, Glycerin, Carthamus Tinctorius (Safflower) Seed Oil, Mentha Citrata Oil, Salicylic Acid, Camellia Sinensis Leaf Extract, Epilobium Angustifolium Flower/Leaf/Stem Extract, Niacinamide, Panthenol, Lavandula Angustifolia (Lavender) Oil, Allium Sativum (Garlic) Bulb Extract, Yeast Ferment Extract, Cocos Nucifera (Coconut) Oil, Citrus Nobilis (Mandarin Orange) Peel Oil, Foeniculum Vulgare (Fennel) Oil, Rosmarinus Officinalis (Rosemary) Leaf Oil, Salvia Sclarea (Clary) Oil, Vanillin, Cetearamidoethyldiethonium Succinoyl Hydrolyzed Pea Protein, Lactobacillus Ferment, Xanthan Gum, Sodium Polyacryloyldimethyl Taurate, Silica Caprylyl Silylate, Sodium Hydroxide, Sodium Polynaphthalenesulfonate, Raphanus Sativus (Radish) Root Extract, Propylene Glycol, Sodium Chloride, Citric Acid, Linalool

KEEP OUT OF THE REACH OF CHILDREN.

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|----------------------|
| PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5) | PYRITHIONE ZINC | 0.125 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------|-----------------|
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:73528-400-03 | 5 mL in 1 PACKET; Type 0: Not a Combination Product | 02/01/2020 | |
| 2 | NDC:73528-400-02 | 30 mL in 1 TUBE; Type 0: Not a Combination Product | 02/01/2020 | |
| 3 | NDC:73528-400-01 | 100 mL in 1 TUBE; Type 0: Not a Combination Product | 02/01/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final | part358H | 02/01/2020 | |

Labeler - Zero Flakes Given, LLC. (116933871)

Revised: 10/2022

Zero Flakes Given, LLC.