# BALANCING- zinc pyrithione shampoo 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.

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## **Balancing Shampoo**

# **Active Ingredient**

Zinc Pyrithione 1.0%

# **Purpose**

Anti-Dandruff

# Warnings

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, conult 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.

#### Uses

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

### **Directions**

Apply to wet hair and scalp. Massage to lather and let sit for 2-3 minutes. Rinse thoroughly. Repeat if desired.

For best results, use at least twice a week or as directed by a doctor.

For maximum dandruff control, use every time you shampoo.

## Questions

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

## **Inactive Ingredients**

Aqua (Water, Eau), Sodium Cocoyl Isethionate, Sodium Lauroamphoacetate, Acrylates Copolymer, Ethylhexyl Olivate, Stearyl Alcohol, Carthamus Tinctorius (Safflower) Seed Oil, Allium Sativum (Garlic) Bulb Extract, Pyrus Malus (Apple) Fruit Extract, Camellia Sinensis Leaf Extract, Panthenol, Citrus Nobilis (Mandarin Orange) Peel Oil, Foeniculum Vulgare (Fennel) Oil, Lavandula Angustifolia (Lavender) Oil, Mentha Citrata Oil, Orbignya Oleifera Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Oil, Salvia Sclarea (Clary) Oil, Vanillin, Cocos Nucifera (Coconut) Oil, Laminaria Saccharina Extract, Squalane, Caprylyl Glycol, Yeast Ferment Extract, Guar Hydroxypropyltrimonium Chloride, Glycerin, Sodium Isethionate, Lactobacillus Ferment, Octenidine HCl, Sodium Polynaphthalenesulfonate, Xanthan Gum, Hexamidine Diisethionate, Ethylhexylglycerin, Coconut Alcohol, Raphanus Sativus (Radish) Root Extract, Arginine, Glycolic Acid, Polyquaternium-73, Pentylene Glycol, Propylene Glycol, Sodium Chloride, Potassium Sorbate, Sodium Benzoate, Citric Acid, Linalool

KEEP OUT OF REACH OF CHILDREN.

# **Principal Display Panel**

**BALANCING SHAMPOO** 

**CLEANS & CALMS** 

jupiter

Dandruff Shampoo with 1% Zinc Pyrithione, Coconut Oil & Algae Extract

0.3 fl oz | 9 ml

**NOURISHING CONDITIONER** 

SMOOTHES & SOOTHES

jupiter

Moisturizing Formula with Probiotics, Vitamin E & Colloidal Oatmeal

0.3 fl oz | 9 ml

A silky, lightweight moisturizer that nourishes the scalp and leaves hair soft, smooth, and tangle-free.

**Directions:** Apply to wet hair after shampooing and gently massage into hair and scalp. Rinse thoroughly. Also recommended for use when not shampooing.

Ingredients: Aqua (Welter, Eau), Cotearyl Alcohol, Dimethicone, G., Cycarin, Glycoryl Stearate, Stearatkonium Dimethicone, G., Cycarin, Glycoryl Stearate, Stearatkonium Carthamus Tinctorius (Safflower) Seed Oil, Argania Spinosa Kennel Oil, Lavandula Angustifola (Lavender) Oil, Camella Sinerais Lead Extract. Cocco Nucléra (Coconul) Citrus Nobilis (Mandarin Orango) Peel Oil, Inga Alba Bark Extract, Rosmerinus Officinalis (Rosmary) Leaf Oil, Salvias Clares (Clary) Oil, Genocarpus Batuas Fruit Oil, Zae Muye Schrae (Clary) Oil, Genocarpus Batuas Fruit Oil, Zae Muye Extract, Foeniculum Yulgare (Fennel) Oil, Lactobacillus Farment, Panthenol, Tocopherol, Veast Fernent Extract. Allium Satvum (Garlic) Bulb Extract, Vanillin, Silicone Acholh, Trideceln 1-2, Citrle Adi, Butylene Glycol, Sodium Lauroyl Lactylate, Sodium Caproyl Lactylate, Polysoubate 60, Disodium Phosphata, Sodium Phosphata, Polysoum Potaspate, Polysoub Polspate, Polysoub Polspate, Polysoub Polspate, Polysoub Polspate, Polysoub Polspate, Polysoum Polspate, Polssaum Polspate, Polssaum Polspate, Polssaum Polspate, Polssaum, Pol

WARNING: Avoid contact with eyes, if contact occurs, rinse well with water.

- Suitable for All Hair Type
   Safe for Color &
- Chemically-Treated Ha
   Sulfate, Paraben &
   Phthalate, Free

For Single Use - Not for Resale

Dist. by Zero Flakes Given, LI New York, NY 10013

# **BALANCING SHAMPOO**

**CLEANS & CALMS** 



Dandruff Shampoo with 1% Zinc Pyrithione, Coconut Oil & Algae Extract

9.5 fl oz | 280 ml

#### **Drug Facts**

Active Ingredient
Pyrithione Zinc 1.0%.....

Purpose .. Anti-dandruff

(e)

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

Warnings

For external use only.

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

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Do not use on children under 2 years of age, unless

Directions

· Apply to wet hair and scalp. Massage to lather and let sit for

- 2-to-3 minutes. Rinse thoroughly. Repeat if desired.

  For best results, use at least twice a week or as directed by a doctor.
- · For maximum dandruff control, use every time you shampoo.
- Suitable for All Hair Types
- Safe for Color & Chemically-Treated Hair
- Sulfate, Paraben & Phthalate-Free

Cruelty-Free & Vegan

#### Inactive Ingredients

Aqua (Water, Eau), Sodium Cocoyl Isethionate, Sodium Lauroamphoacetate, Acrylates Copolymer, Ethylhexyl Olivate, Stearyl Alcohol, Carthamus Tinctorius (Safflower) Seed Oil. Allium Sativum (Garlic) Bulb Extract, Pyrus Malus (Apple) Fruit Extract, Camellia Sinensis Leaf Extract, Panthenol, Citrus Nobilis (Mandarin Orange) Peel Oil, Foeniculum Vulgare (Fennel) Oil, Lavandula Angustifolia (Lavender) Oil, Mentha Citrata Oil, Orbignya Oleifera Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Oil, Salvia Sclarea (Clary) Oil, Vanillin, Cocos Nucifera (Coconut) Oil, Laminaria Saccharina Extract. Squalane, Caprylyl Glycol, Yeast Ferment Extract, Guar Hydroxypropyltrimonium Chloride, Glycerin, Sodium Isethionate, Lactobacillus Ferment, Octenidine HCI, Sodium Polynaphthalenesulfonate, Xanthan Gum, Hexamidine Diisethionate, Ethylhexylglycerin, Coconut Alcohol, Raphanus Sativus (Radish) Root Extract, Arginine, Glycolic Acid, Polyquaternium-73, Pentylene Glycol, Propylene Glycol, Sodium Chloride, Potassium Sorbate, Sodium Benzoate, Citric

Questions?

1-877-NoFlake (1-877-663-5253)

Dist. by Zero Flakes Given, LLC New York, NY 10013 Made in the U.S.A. HelloJupiter.com

# **BALANCING**

zinc pyrithione shampoo

<b>Product</b>	Inform	ation
Product	morm	ation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73528-100

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5) PYRITHIONE ZINC 1 g in 100 mL

# **Inactive Ingredients**

Ingredient Name Strength

WATER (UNII: 059QF0KO0R)

# **Packaging**

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	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:73528- 100-01	280 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	02/01/2020		
	2	NDC:73528- 100-02	85 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	02/01/2020		
	3	NDC:73528- 100-03	9 mL in 1 PACKET; Type 0: Not a Combination Product	02/01/2020		

# Marketing Information

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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.