

**FLAKES CEDAR MINT ANTI DANDRUFF- pyrithione zinc lotion/shampoo
Cosco International, 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.

Flakes Cedar Mint Anti Dandruff Shampoo

DRUG FACTS

Active Ingredients: **Purpose:**

Pyrrhithione Zinc 2%.....Anti dandruff

☐ **Use:** For the control of the symptoms of dandruff and or seborrheic dermatitis

☐ **Warnings**

for external use only

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

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.

Directions: for best results, use at least twice a week or as directed by a doctor.

- Wet hair thoroughly
- Massage a liberal amount into your scalp
- Leave lather on scalp for several minutes
- Rinse and repeat.

Inactive Ingredients:

WATER, SODIUM C14-16 OLEFIN SULFONATE, COCAMIDOPROPYL BETAINE, COCO MONOETHANOLAMIDE, FRAGRANCE, GLYCERIN, PHENOXYETHANOL, PEPPERMINT OIL, HYDROXYPROPYL GUAR, HYDROXYPROPYL TRIMONIUM CHLORIDE, CAPRYLYL GLYCOL, POLYACRYLATE CROSSPOLYMER-6, METHYL DIISOPROPYL PROPIONAMIDE, TEA TREE OIL, CITRIC ACID

☐ **Questions?**

help@byeflakes.com

Other Information

Store at room temperature between 68-77°F (20-25°C).

Do not expose to excessive heat

266ml NDC: 52261-1400-1

CEDAR MINT

Anti-Dandruff Shampoo

With pyrithione zinc and peppermint oil

For great hair

9 fl. oz. 266mL NEW YORK

Flakes

The best science. The best thing to happen to guys with dandruff since bats.

Text "MORE PLEASE" to re-order.

(917) 952-5480

Pro tip: Wait to text until after you shower.

Our formula was designed by dermatologists with great hair to create the ultimate shampoo. Pyrithione zinc eliminates dandruff-causing fungus and then cooling peppermint oil gives your scalp a refreshing finish.

Drug Facts	Inactive Ingredients
Active Ingredient: Pyrithione Zinc - 2%..... Purpose: Anti dandruff	Water, Sodium C14-16 Olefin Sulfonate, Cocamidopropyl Betaine, Coco Monoethanolamide, Fragrance, Glycerin, Phenoxyethanol, Peppermint Oil, Hydroxypropyl Guar, Hydroxypropyltrimonium Chloride, Caprylyl Glycol, Polyacrylate Crosspolymer-6, Methyl Diisopropyl Propionamide, Tea Tree Oil, Citric Acid
Use: for the control of the symptoms of dandruff and or seborrheic dermatitis.	Questions? help@byeflakes.com.....(917) 581-4875
Warnings for external use only.	Other information: store at room temperature between 68-78°F (20-25°C). Do not expose to excessive heat.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.	<ul style="list-style-type: none"> Clinical Strength Daily Therapeutic Shampoo Fast Acting Gentle Formula No Sulfates, No Parabens, No Phthalates Natural Fragrance Made in U.S.A. with global components
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.	
Directions: for best results, use every other day or as directed by a doctor. <ul style="list-style-type: none"> Wet hair thoroughly Massage a liberal amount into your scalp Leave lather on scalp for several minutes Rinse and repeat 	



Manufactured for: Flakes, Inc., Brooklyn, NY 11249

FLAKES CEDAR MINT ANTI DANDRUFF

pyrithione zinc lotion/shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52261-1400
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	0.02 kg in 1 kg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GUARAPROLOSE (1300 MPA.S AT 1%) (UNII: 1530WMS90S)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
GLYCERIN (UNII: PDC6A3C0OX)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

TEA TREE OIL (UNII: VIF565UC2G)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52261-1400-1	0.266 kg in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	12/01/2022	

Labeler - Cosco International, Inc. (016433141)

Registrant - Cosco International, Inc. (016433141)

Establishment

Name	Address	ID/FEI	Business Operations
Cosco International, Inc.		016433141	manufacture(52261-1400) , label(52261-1400) , pack(52261-1400)

Revised: 12/2022

Cosco International, Inc.