

DZUL ANTI-DANDRUFF- zinc pyrithione shampoo
Caball Sales, 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.

83037-001-08

Zinc Pyrithione 1%

Anti-Dandruff

For the relief of the symptoms of dandruff.

For external use only.

Do not use on wounds or damaged skin or on a child under 12 years of age unless directed by a physician.

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

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

If swallowed, get medical help or contact Poison Control Center right away.

Apply a small amount quantity of the product into hair and massage the scalp.

Rinse thoroughly with enough water, repeat if needed.

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

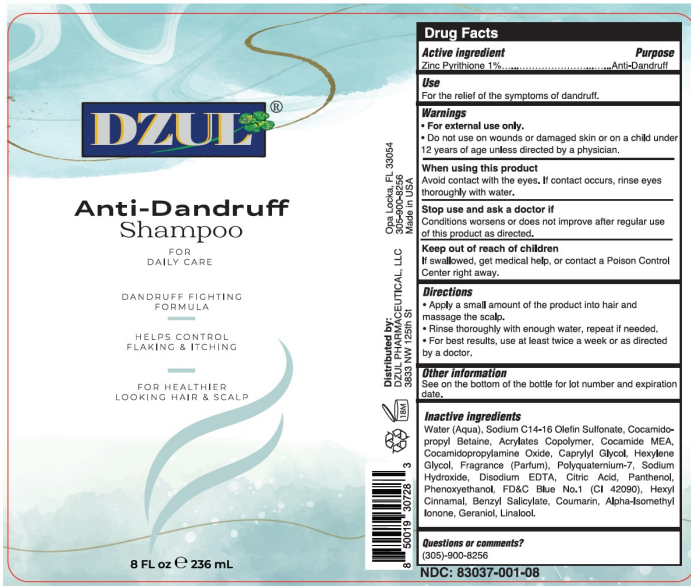
See on the bottom of the bottle for lot number and expiration date.

Water (Aqua), Sodium C14-16 Olefin Sulfonate, Cocamidopropyl Betaine, Acrylates Copolymer, Cocamide MEA, Cocamidopropylamine Oxide, Caprylyl Glycol, Hexylene Glycol, Fragrance (Parfum), Polyquaternium-7, Sodium Hydroxide, Disodium EDTA, Citric Acid, Panthenol, Phenoxyethanol, FD&C Blue No.1 (CI 42090), Hexyl Cinnamal, Benzyl Salicylate, Coumarin, Alpha-Isomethyl Ionone, Geraniol, Linalool.

QUESTION OR COMMENTS?

Call (305)-900-8256

DZUL ANTI-DANDRUFF SHAMPOO



Drug Facts

Active Ingredient	Purpose
Zinc Pyrithione 1%	Anti-Dandruff
Use	
For the relief of the symptoms of dandruff.	
Warnings	
• For external use only.	
• Do not use on wounds or damaged skin or on a child under 12 years of age unless directed by a physician.	
When using this product	
Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water.	
Stop use and ask a doctor if	
Conditions worsen 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	
• Apply a small amount of the product into hair and massage the scalp.	
• Rinse thoroughly with enough water, repeat if needed.	
• For best results, use at least twice a week or as directed by a doctor.	
Other information	
See on the bottom of the bottle for lot number and expiration date.	
Inactive ingredients	
Water (Aqua), Sodium C14-16 Olefin Sulfonate, Cocamidopropyl Betaine, Acrylates Copolymer, Cocamide MEA, Cocamidopropylamine Oxide, Caprylyl Glycol, Hexylene Glycol, Fragrance (Parfum), Polyquaternium-7, Sodium Hydroxide, Disodium EDTA, Citric Acid, Panthenol, Phenoxyethanol, FD&C Blue No.1 (CI 42090), Hexyl Cinnamal, Benzyl Salicylate, Coumarin, Alpha-Isomethyl Ionone, Geraniol, Linalool.	
Questions or comments?	
(305)-900-8256	
NDC: 83037-001-08	

DZUL ANTI-DANDRUFF

zinc pyrithione shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83037-001
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
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X60370K2I)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	

COCAMIDOPROPYLAMINE OXIDE (UNII: M4SL82J7HK)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
LINALOOL, (+)- (UNII: F4VNO44C09)
BENZYL SALICYLATE (UNII: WAO5MKNK9TU)
COUMARIN (UNII: A4VZ22K1WT)
PANTHENOL (UNII: WW9CM0067Z)
GERANIOL (UNII: L837108USY)
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
EDETATE DISODIUM (UNII: 7FLD91C86K)
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83037-001-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M032	09/22/2023	

Labeler - Caball Sales, Inc. (047422138)

Revised: 9/2023

Caball Sales, Inc.