

GLOBAL KERATIN - ANTI-DANDRUFF- zinc pyrithione shampoo
Tibolli 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.

74781-010-85

Zinc Pyrithione 1%

Anti-Dandruff

Helps prevent recurrence of flaking and itching associated with 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.

QUESTION OR COMMENTS?

Call: 1. 888.JUVENIX(888-588-3946)/305-390-0044

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, Keratin, Hydrolyzed Keratin, Oxidized Keratin, Disodium EDTA, Citric Acid, Panthenol, Phenoxyethanol, FD&C Blue No.1 (CI 42090), Hexyl Cinnamal, Benzyl Salicylate, Coumarin, Alpha-Isomethyl Ionone, Geraniol, Linalool.

Contact us

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GK HAIR ANTI-DANDRUFF SHAMPOO

NDC 74781-010-85



PRO LINE
HAIR TAMING SYSTEM
WITH JUVEXTIN™

ANTI-DANDRUFF SHAMPOO

Champi Antipar Shampoo Antiparicida

250 ml 8.5 fl. oz.

Drug Facts

Active ingredient Zinc Pyrithione 1%	Purpose Anti-Dandruff
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Use
Helps prevent recurrence of flaking and itching associated with 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:
• Condition worsens 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 quantity of the product and lather 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 Chloride, 1,4-16 Olefin Sulfonate, Cocamidopropyl Betaine, Acrylates Copolymer, Cocamide DEA, Cocamidopropylamine Oxide, Citric Acid, Polyethylene Glycol, Fragrance, Carbonyl Glycol, Hexylene Glycol, Phosphoric Acid, Polyacrylamide, Sodium Hydroxide, Potassium Hydroxide, Keratin, Oxidized Keratin, Disodium EDTA, Citric Acid, Sorbitol, Phenolphthalein, Ethoxyl Stearic Acid (CI 42000), Hexyl Cinnamal, Benzyl Salicylate, Coumarin, Alpha-Isothymyl Isonicotinamide, Linalool.

Questions? Contact us
Call 1-888-824-9888 (888-388-3849) 905-399-0244

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GK Hair, LLC Florida, Lauderdale, FL, USA
TBCO,LLC Puerto Rico, USA | Made in USA / Hecho en EE.UU.
WVA TBCO,LLC Ltd.
Broombridge Business Center 288,
Barnow Road, Dublin 7 Ireland



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GLOBAL KERATIN - ANTI-DANDRUFF

zinc pyrithione shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74781-010
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 g

Inactive Ingredients

Ingredient Name	Strength
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6037OK2I)	
COCAMIDOPROPYLAMINE OXIDE (UNII: M4SL82J7HK)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
LINALOOL, (+)- (UNII: F4VNO44C09)
BENZYL SALICYLATE (UNII: WAO5MKN9TU)
COUMARIN (UNII: A4VZ22K1WT)
PANTHENOL (UNII: WW9CM0O67Z)
GERANIOL (UNII: L837108USY)
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
EDETATE DISODIUM (UNII: 7FLD91C86K)
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74781-010-85	241 g in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M032	04/30/2020	

Labeler - Tibolli LLC (080403473)

Registrant - CHEMCO CORPORATION (032495954)

Establishment

Name	Address	ID/FEI	Business Operations
CHEMCO CORPORATION		032495954	manufacture(74781-010)