BASIC ESSENTIALS DANDRUFF (CLEAN AND CONDITIONER) 2 IN 1 EVERYDAY CLEAN- pyrithione zinc shampoo Filo America

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.

Drug Facts

Active Ingredient Purpose

Zinc Pyrithione 1% Anti-dandruff

Helps prevent recurrence of flaking and itching associated with dandruff.

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

Do not get into eyes, if contact occurs, rinse eyes thoroughly with water.

Shake well, wet hair, massage onto scalp. Rinse, repeat if desired.

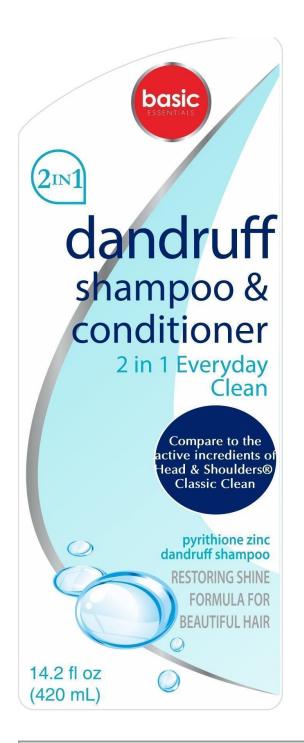
For best results, use at least twice a week or as directed by a doctor.

For maximum dandruff control, use every time you shampoo.

For external use only.

Stop use and ask a doctor if Condition worsens or does not improve after regular use as directed. apply as needed.

water, sodium laureth sulfate, cocamidopropyl betaine, sodium lauroamphoacetate, glycol stearate, acrylates/acrylamide copolymer, ammonium chloride, methylchloroisothiazolinone, methylisothiazolinone, fragrance, citric acid, guar hydroxypropyltrimonium chloride, titanium dioxide, disodium EDTA, zinc chloride, blue 1, red 4





Drug Facts Active ingredient

Purpose

When using this product
• do not get into eyes. If contact occurs, rinse eyes thoroughly with water.
Stop use and ask a doctor if

scop use and ask a doctor in condition worsens or does not improve after regular use as directed. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

- shake well. Wet hair. Massage onto scalp. Rinse. 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.

Inactive ingredients Water, Ammonium Laureth Sulfate, Ammonium Lauryl Sulfate, Amodimethicone, Sodium Chloride, Glycol Distearate, Cetyl Alcohol, Cocamide MeA, Fragrance, Polyquaternium-10, Sodium Citrate, Hydrogenated Polydecene, Sodium Benzoate, Trideceth-12, Cetrimonium Chloride, Citric Acid, Ammonium Xylenesulfonate, Ext, D&C Violet No. 2, FD&C Blue No.1, Benzyl Alcohol Methylchloroisothiazolinone, Methylisothiazolinone.

*This product is not manufactured or distributed by Procter & Gamble distributor of Head & Shoulder

Distributed By:

Filo America, P.O.Box 23592 Los Angeles, CA 90023 **Questions or Comments?**

1.866.460.0322



BASIC ESSENTIALS DANDRUFF (CLEAN AND CONDITIONER) 2 IN 1 **EVERYDAY CLEAN**

pyrithione zinc shampoo

Product Information

Product Type HUMAN OTC DRUG NDC:50438-606 Item Code (Source)

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

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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)		
cocamidopropyl betaine (UNII: 5OCF3O11KX)		
glycol stearate (UNII: 0324G66D0E)		
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)		
ammonium chloride (UNII: 01Q9PC255D)		
methylchloroisothiazolinone (UNII: DEL7T5QRPN)		
methylisothiazolinone (UNII: 229 D0 E1QFA)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)		
ZINC CARBO NATE (UNII: EQR32Y7H0 M)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
GUAR HYDRO XYPRO PYLTRIMO NIUM CHLO RIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16 G315W7A)		
SODIUM XYLENESULFONATE (UNII: G4LZF950 UR)		
MAGNESIUM CARBO NATE HYDRO XIDE (UNII: YQO029V1L4)		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:50438-606-01	420 mL in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part358H	06/10/2015		

Labeler - Filo America (943873703)

Registrant - NINGBO PULISI DAILY CHEMICAL PRODUCTS CO., LTD. (529047265)

Establishment				
Name	Address	ID/FEI	Business Operations	
NINGBO PULISI DAILY CHEMICAL PRODUCTS CO., LTD.		529047265	manufacture(50438-606)	

Revised: 6/2015 Filo America