BASIC ESSENTIALS DANDRUFF 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





Everyday Clean

Drug Facts

Active ingredient

Purpose

Use helps prevent recurrence of flaking and itching associated with dandruff

Warnings

or external use only

When using this product

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

Stop use and ask a doctor if 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, sodium laureth sulfate, sodium lauryl sulfate, cocamide MEA, zinc carbonate, glycol distearate,, amodimethicone, fragrance, cetyl cocamine MEA, zinc caroniare, gyror disetatare, amboninetinorie, negranoe, very alcohol, guar hydroxypropytrimonium chloride, magnesium sulfate, sodium benzoate magnesium carbonate hydroxide, ammonium laureth sulfate, benzyl alcohol, sodium chloride, trideceth-12, cetrimonium chloride, methylchlorosiothiazolinone, methylsothiazolinone, sodium xylenesulfonate, blue 1, red 4.

*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 EVERYDAY CLEAN

pyrithione zinc shampoo

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50438-605

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)	
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 MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	
ZINC CARBONATE (UNII: EQR32Y7H0 M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GUAR HYDRO XYPRO PYLTRIMO NIUM CHLO RIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
SODIUM XYLENESULFONATE (UNII: G4LZF950 UR)	
MAGNESIUM CARBO NATE HYDRO XIDE (UNII: YQO029 V1L4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

l	Packaging				
ı	# Ite	em Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:	50438-605-01	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(50438-605)	

Revised: 6/2015 Filo America