

BASIC ESSENTIALS DANDRUFF EVERYDAY CLEAN- pyrrithione 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 Pyrrithione 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.

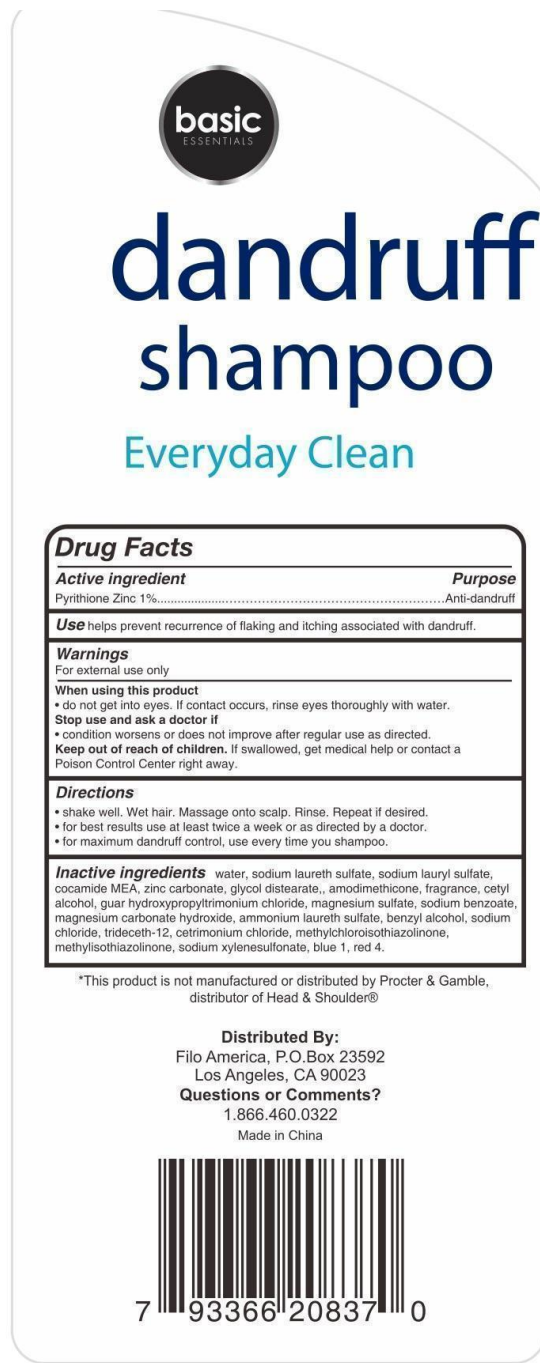
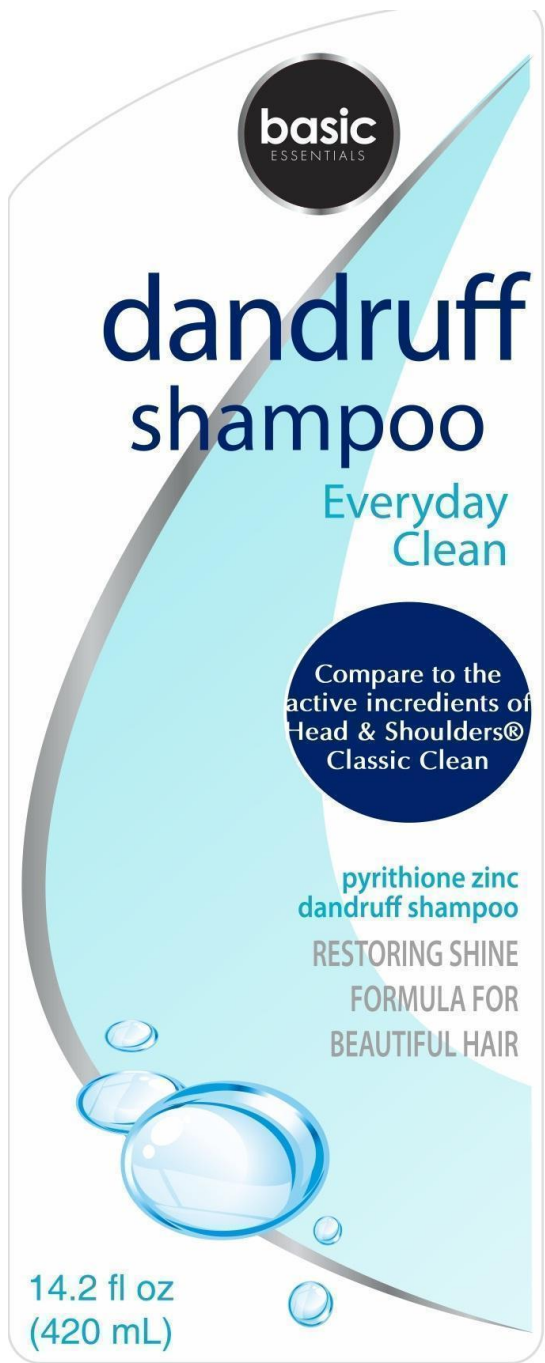
For maximum dandruff control, use every time you shampoo.

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, methylchloroisoethiazolinone, methylisoethiazolinone, fragrance, citric acid, guar hydroxypropyltrimonium chloride, titanium dioxide, disodium EDTA, zinc chloride, blue 1, red 4



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: 059QF0K00R)	
cocamidopropyl betaine (UNII: 5OCF3O11KX)	
glycol stearate (UNII: 0324G66D0E)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
ammonium chloride (UNII: 01Q9PC255D)	
methylchloroisothiazolinone (UNII: DEL7T5QRPN)	
methylisothiazolinone (UNII: 229D0E1QFA)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
ZINC CARBONATE (UNII: EQR32Y7H0M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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