

**BASIC ESSENTIALS DANDRUFF DRY SCALP- 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.*

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**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.

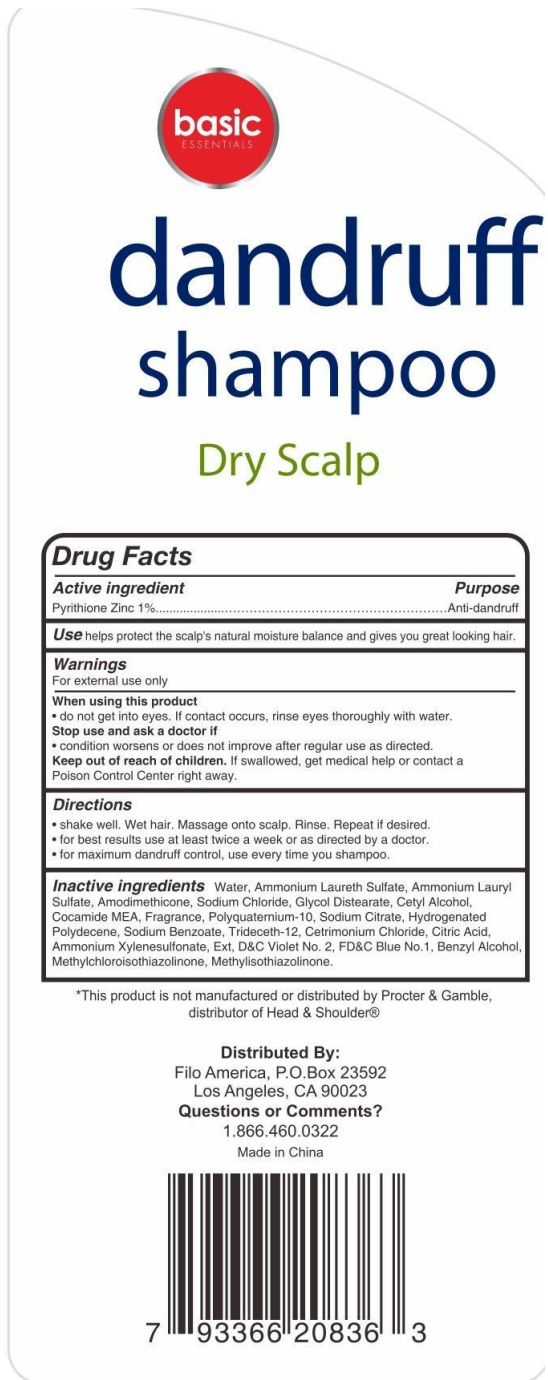
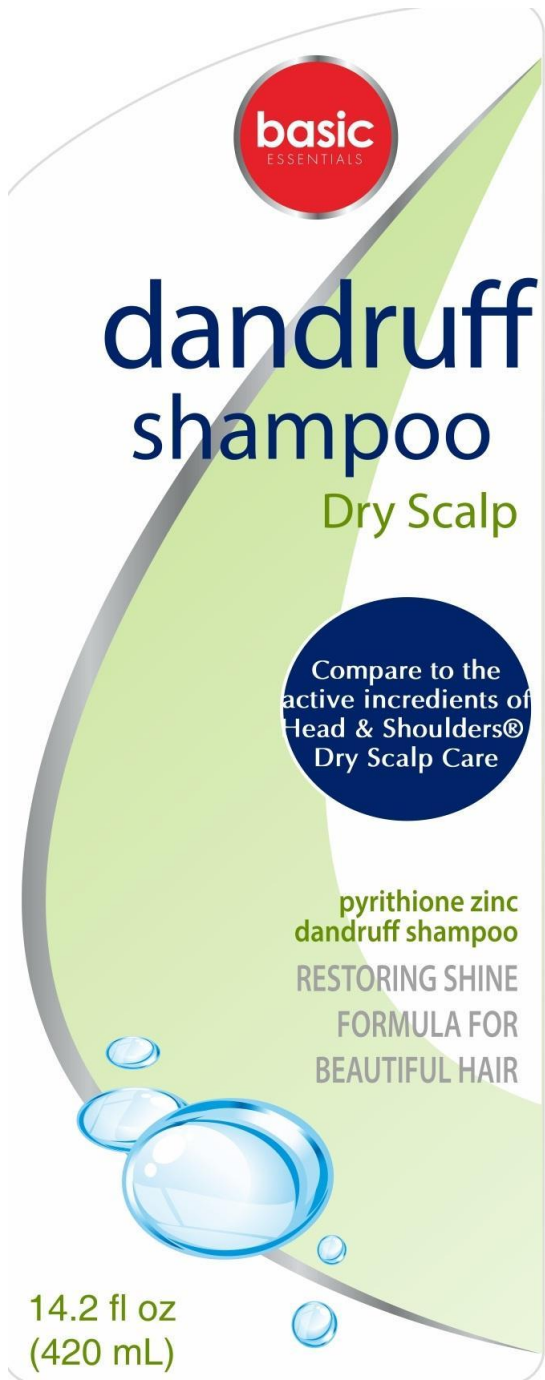
For maximum dandruff control, use every time you shampoo.

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



<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Pyrithione Zinc 1%	Anti-dandruff
<b>Use</b> helps protect the scalp's natural moisture balance and gives you great looking hair.	
<b>Warnings</b>	
For external use only	
<b>When using this product</b>	
• do not get into eyes. If contact occurs, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor if</b>	
• condition worsens or does not improve after regular use as directed.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
• 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.	
<b>Inactive ingredients</b> 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  
 Made in China



<b>BASIC ESSENTIALS DANDRUFF DRY SCALP</b>			
pyrithione zinc shampoo			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50438-607
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
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: 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:50438-607-01	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(50438-607)

Revised: 6/2015

Filo America