

ROYAL DANDRUFF DRY SCALP CARE- 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
Pyrithione Zinc 1%	Anti-dandruff

Help prevent the scalp's natural moisture balance and gives you great looking hair.

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, methylchloroisoithiazolinone, methylisothiazolinone, fragrance, citric acid, guar hydroxypropyltrimonium chloride, titanium dioxide, disodium EDTA, zinc chloride, blue 1, yellow 5



ROYAL DANDRUFF DRY SCALP CARE

pyrithione zinc shampoo

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:50438-300

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: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50438-300-01	350 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	09/17/2013	

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(50438-300)