XTRACARE ANTI-DANDRUFF HAIR CLEANSE FOR NORMAL HAIR- pyrithione zinc shampoo My Import USA Inc

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.

Active Ingredient Purpose

Pyrithione zinc 0.5% Anti-dandruff

XtraCare Anti-Dandruff Shampoo + pyrithione zinc

nourishing coconut & shea butter

fight flakes leaving hair healthy & shiny

□ **Keep out of reach of children.** □ If swallowed, get medical help or contact a Poison Control Center right away.

Uses helps prevent recurrence of flaking and itching associated with dandruff.

Gentle enough for everyday use. For best results, use with XtraCare nourishing coconut & shea butter conditioner.

WARNINGS

For external use only

When using this product Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

□**Stop use and ask a doctor if**□ Condition worsens or does not improve after regular use of this product as directed.

Directions

Wet hair, massage onto scalp, rinse. Repeat if desired. For best results use at least twice a week or as directed by a doctor.

Inactive Ingredients

water, sodium laureth sulfate, cocamidopropyl betaine, sodium chloride, cocamide MEA, lauryl methyl gluceth-10, glycerin, carbomer, DMDM hydantoin, fragrance, triethanolamine, disodium EDTA, cocos nucifera (coconut) fruit extract, shea nut butter.

Other information

store at 20°C to 25°C (68° to 77°F)



ANTI-DANDRUFF SHAMPOO + PYRITHIONE ZINC

NORMAL HAIR

Drug Facts

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Inactive Ingredients

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Chloride, Cocamide MEA, Lauryl Methyl Gluceth-10, Glycerin,Carbomer, DMDM Hydantoin, Fragrance, Triethanolamine, Disodium EDTA, FD&C Blue No.1.



DISTRIBUTED BY:
REJOICE INTERNATIONAL INC.
48325 BINGHAMPTON DR,
NORTHVILLE, MI 48168, USA
MADE IN CHINA

XTRACARE ANTI-DANDRUFF HAIR CLEANSE FOR NORMAL HAIR

pyrithione zinc shampoo

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51628-0002

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
	PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	20 mg in 400 mg

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390 UAP0)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11KX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
.BETAD-GLUCO PYRANO SE (UNII: J4R0 0 M8 14D)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
DMDM HYDANTO IN (UNII: BYR0546 TOW)	
TROLAMINE (UNII: 903K93S3TK)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:51628-0002-1	400 mg in 1 BOTTLE				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part358H	10/09/2013		

Labeler - My Import USA Inc (195767988)

Establishment				
Name	Address	ID/FEI	Business Operations	
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(51628-0002)	

Revised: 10/2013 My Import USA Inc