DANDRUFF- pyrithione zinc shampoo
Xtreme Tools International, 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.

DANDRUFF SHAMPOO

Active Ingredient

Pyrithione zinc 2%

Purpose

Anti-dandruff

Use

Helps prevent itching and flaking associated with dandruff.

Warning

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.

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

Directions

- shake well
- For best results use at least twice a week or as directed by a doctor

Inactive Ingredients

Water, Sodium C14-16 Olefin Sulfonate, Cocamidopropyl Betaine, Cocamide MEA, Glycol Distearate, Polysorbate 20,PPG-10 Cetyl Ether, PEG-8, Polyquaternium-10, Acrylates, Vinyl Neodecanoate, Crosspolymer, Hydrolyzed Wheat Protein, Ricinus Communis (Castor) Seed Oil, Hydrolyzed Keratin, Chitosan Succinamide, Argania Spinosa (Argan) Kernel Oil, Olea Europaea (Olive) Oil, Sodium Benzoate, Pottassium Sorbate, Fragrance, Citric Acid, CI 42090

Questions or comments?

Call 1-305-622-7474, Monday through Friday 9:00 AM to 5:00 PM

PACKAGE LABEL

473 mL in Bottle; NDC 74553-003-01

DANDRUFF

pyrithione zinc shampoo

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74553-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	2 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ARGAN OIL (UNII: 4V59G5UW9X)	
OLIVE OIL (UNII: 6UYK2W1W1E)	

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
PPG-10 CETYL ETHER (UNII: Q056X4917J)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW) (UNII: J2S07SB0YL)	
COCODIMONIUM HYDROXYPROPYL HYDROLYZED KERATIN (1000 MW) (UNII: 8V0I3U3HMO)	
POLYQUATERNIUM-10 (125 MPA.S AT 2%) (UNII: L45WU8S981)	
ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
VINYL NEODECANOATE (UNII: 9NDY01YYPT)	
CASTOR OIL (UNII: D5340Y2I9G)	
CHITOSAN SUCCINAMIDE (1300 MPA.S) (UNII: 41164V2SNS)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74553-003-01	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	10/06/2020	

Labeler - Xtreme Tools International, Inc (125398904)

Registrant - Xtreme Tools International, Inc (125398904)

Establishment

Name	Address	ID/FEI	Business Operations
Xtreme Tools International, Inc		125398904	manufacture(74553-003)

Revised: 10/2020 Xtreme Tools International, Inc