

AXE FREEZE ANTIDANDRUFF- pyrithione zinc shampoo
Conopco Inc. d/b/a Unilever

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.

Axe Freeze Anti-Dandruff shampoo+conditioner

Active Ingredient

Pyrithione Zinc (1.0%)

Purpose

Anti-dandruff

Use

controls scalp itching and flaking associated with dandruff

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.

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

Directions

- Squeeze. Lather. Rinse
- For best results, use at least twice a week or as directed by a doctor.

Inactive ingredients

Water (Aqua), Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Chloride, Fragrance (Parfum), Carbomer, Dimethiconol, Glycol Distearate, Menthol, DMDM Hydantoin, Guar Hydroxypropyltrimonium Chloride, TEA-Dodecylbenzenesulfonate, Citric Acid, Iodopropynyl Butylcarbamate, Methylchloroisothiazolinone, Methylisothiazolinone, PPG-9, Mica (CI 77019), Titanium Dioxide (CI 77891), Blue 1 (CI 42090), Red 33 (CI 17200)

theaxeeffect.com

QUESTIONS/COMMENTS?

1-800-450-7580

PDP 12 oz front



PDP 12 oz back

AXE
FREEZE
 Anti-Dandruff
 Scalp Cooling
 2 in 1 Shampoo + Conditioner



Directions: Wash, Attract, Repeat.

FPO MESSY? SPIKEY?
 SMOOTH & SOPHISTICATED?
 AXE has the styling product
 for the look you want.

Drug Facts

Active Ingredient	Purpose
Pyrrithione Zinc (1.0%).....	Anti-dandruff

Use controls scalp itching and flaking associated with dandruff.

**SEE INSIDE FOR
 ADDITIONAL DRUG FACTS**

theaxeffect.com
 QUESTIONS/COMMENTS? 1-800-450-7580

 Bottle coded for recycling. Check if facilities exist.
 Dist. by © Unilever
 Trumbull, CT 06611 Made in USA



0 79400 06694 7

HINGE AREA / NO COPY

GLUE AREA = .328" X 4.567"

Drug Facts (cont'd)

Warnings
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Directions

- Squeeze, Lather, Rinse.
- For best results, use at least twice a week or as directed by a doctor.

Inactive ingredients
 Water (Aqua), sodium laureth sulfate, cocamidopropyl betaine, sodium chloride, fragrance (parfum), carbomer, dimethiconol, glycol distearate, menthol, DMDM hydantoin, guar hydroxypropyltrimonium chloride, TEA-dodecylbenzenesulfonate, citric acid, iodopropynyl butylcarbamate, methylchloroisothiazolinone, methylisothiazolinone, PPG-9, mica (CI 77019), titanium dioxide (CI 77891), blue 1 (CI 42090), red 33 (CI 17200).

GLUE AREA / NO COPY

GLUE AREA = .265" X 4.567"

AXE FREEZE ANTIDANDRUFF

pyrrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64942-1185
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Pyrithione Zinc (UNII: R953O2RHZ5) (Pyrrithione - UNII:6GK82EC25D)	Pyrrithione Zinc	1 mL in 100 mL
Inactive Ingredients		
Ingredient Name		Strength
WATER (UNII: 059QF0KO0R)		
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)		
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)		
GLYCOL STEARATE (UNII: 0324G66D0E)		
MENTHOL (UNII: L7T10EIP3A)		
DMDM HYDANTOIN (UNII: BYR0546TOW)		
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)		
TEA-DODECYLBENZENESULFONATE (UNII: 8HM7ZD48HN)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)		
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)		
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)		
PPG-9 (UNII: I29VQH0G0B)		
MICA (UNII: V8A1AW0880)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64942-1185-1	355 mL in 1 CONTAINER		
2	NDC:64942-1185-2	50 mL in 1 CONTAINER		
3	NDC:64942-1185-3	443 mL in 1 CONTAINER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	08/02/2009	

Labeler - Conopco Inc. d/b/a Unilever (001375088)

Establishment			
Name	Address	ID/FEI	Business Operations
Unilever Supply Chain Co. d/b/a Unilever		043510056	manufacture