# CLEAR MEN STRONG AND FULL 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.

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## Clear Men Strong and Full Anti Dandruff Shampoo PDP and drug facts box

#### **Active Ingredient**

Pyrithione Zinc (1.0%)

## **Purpose**

Antidandruff

**Uses:** helps prevent and control recurrence of 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 this and all drugs out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions:** Wet hair, massage into scalp, rinse. Repeat if desired. 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)

Dimethiconol

Carbomer

Dimethicone

Sodium Lauroyl Isethionate

Helianthus Annuus (Sunflower) Seed Oil

DMDM Hydantoin

Guar Hydroxypropyltrimonium Chloride

Stearic Acid

Citric Acid

Tallow Acid or Palmitic Acid

Zinc Sulfate

TEA-Dodecylbenzenesulfonate

Sodium Isethionate

Poloxamer 407

Laureth-23

Laureth-4

Tocopheryl Acetate

Prunus Amygdalus Dulcis (Sweet Almond) Oil

PPG-9

Panthenol
Lysine HCl
Hydrogenated Coconut Oil
Glycine Soja (Soybean) Oil
Methylisothiazolinone
PEG-9M
Xanthan Gum
Methylchloroisothiazolinone
Panax Ginseng Root Extract
Mentha Viridis (Spearmint) Leaf Oil
Melaleuca Alternifolia (Tea Tree) Flower/Leaf/Stem Extract
Titanium Dioxide (CI 77891)

**Questions, comments?:** 1-800-372-6389

PDP front





### CLEAR MEN STRONG AND FULL ANTIDANDRUFF

pyrithione zinc shampoo

# Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:64942-1249

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Pyrithione Zinc (UNII: R953O2RHZ5) (Pyrithione - UNII:6GK82EC25D)	Pyrithione Zinc	1.0 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)		
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11KX)		

**SODIUM CHLORIDE** (UNII: 451W47IQ8X) TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) SODIUM LAURO YL ISETHIO NATE (UNII: M590021Z02) **DMDM HYDANTO IN (UNII: BYR0546 TOW)** TEA-DO DECYLBENZENES ULFO NATE (UNII: 8 HM7ZD48 HN) SUNFLOWER OIL (UNII: 3W1JG795YI) CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP) **PPG-9** (UNII: I29 VQ H0 G0 B) METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN) METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA) SPEARMINT OIL (UNII: C3M81465G5) GUAR HYDRO XYPRO PYLTRIMO NIUM CHLO RIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16 G315W7A) STEARIC ACID (UNII: 4ELV7Z65AP) PALMITIC ACID (UNII: 2V16EO95H1) ZINC SULFATE (UNII: 89DS0H96TB) DIMETHICO NOL (41 MPA.S) (UNII: 343C7U75XW) **DIMETHICO NE (UNII: 92RU3N3Y10) SODIUM ISETHIONATE** (UNII: 3R36J71C17) POLOXAMER 407 (UNII: TUF2IVW3M2) LAURETH-23 (UNII: N72LMW566G) **LAURETH-4** (UNII: 6HQ855798J) .ALPHA.-TO COPHERO L ACETATE, D- (UNII: A7E6112E4N) ALMOND OIL (UNII: 66YXD4DKO9) POLYETHYLENE GLYCOL 400000 (UNII: 439 X29 GCJZ) PANTHENOL (UNII: WV9CM0O67Z) LYSINE HYDRO CHLO RIDE (UNII: JNJ23Q2COM) HYDROGENATED COCONUT OIL (UNII: JY810XM10M) SOYBEAN OIL (UNII: 241ATL177A) XANTHAN GUM (UNII: TTV12P4NEE) ASIAN GINSENG (UNII: CUQ3A77YXI) TEA TREE OIL (UNII: VIF565UC2G)

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64942-1249-1	381 mL in 1 CONTAINER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	05/09/2012	

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

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