# MEDACLEAR- zinc pyrithione shampoo Amico Educational Concepts, 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.

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# **Medaclear Shampoo**

# **Active ingredient**

Zinc Pyrithione 1.5%

# Purpose

Antidandruff and Antisebborrheic Dermatitis

#### Use

helps prevent the symptoms from dandruff and/or Seborrheic Dermatitus such as itching, flaking, irritation and redness.

# **Warnings**

# For external use only

# Ask a doctor before use

if you have seborrheic dermatitis that covers a large area of the body.

On children under 2 years of age.

# 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.

# Keep 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 maximum dandruff control, use every time you shampoo. For best results, use twice a week, or as directed by a doctor.

### Other information

Shampoo Scalp & Skin Treatment

Medicated Formula

Treatment for:

Flaking Scalp & Skin

- Oily Scalp
- Itchy Scalp

# Symptom Relief for:

• Seborrheic Dermatitus and Psoriasis

# **Inactive ingredients**

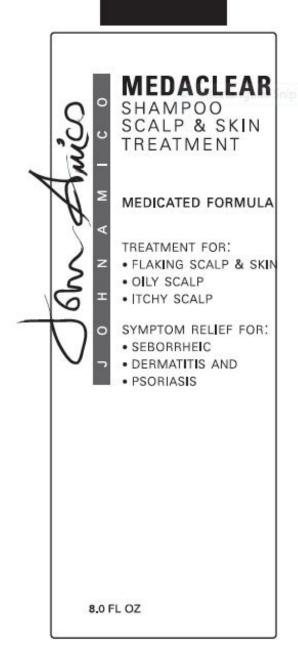
Citric Acid, Cocamide DEA, DMDM Hydantoin, Dyes, Ethylene Glycol Monostearate, Fragrance, Purified Water, Sodium Chloride, TEA Lauryl Sulfate

# Questions?

1-800-JohnAmico

# **Principal Display Panel**

8oz label:



# Drug Facts

## Active Ingredient

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#### Questions? 1-800-JohnAmico

Distributed by John Amico Haircare Products 4731 W, 136th Street, Crestwood, IL 60445 www.johnamico.com

**8oz Label** 

# Distributed By

John Amico Haircare Products 4731 W. 136th Street, Crestwood, IL 60445 www.johnamico.com

# **MEDACLEAR**

zinc pyrithione shampoo

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:51290-011 Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	15.0 g in 1.0 L		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
DMDM HYDANTO IN (UNII: BYR0 546 TOW)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TROLAMINE LAURYL SULFATE (UNII: E8458C1KAA)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51290-011-08	0.24 L in 1 BOTTLE		
2	NDC:51290-011-32	0.95 L in 1 BOTTLE		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH FINAL	part358H	09/08/2010			

# Labeler - Amico Educational Concepts, Inc. (127642333)

# **Registrant** - Continental Manufacturing Chemist, Inc. (005278007)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Continental Manufacturing Chemist, Inc.		005278007	MANUFACTURE(51290-011)		

Revised: 12/2011 Amico Educational Concepts, Inc.