

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.

Medaclear Shampoo

Active ingredient

Zinc Pyrithione 1.5%

Purpose

Antidandruff and Antiseborrheic Dermatitis

Use

helps prevent the symptoms from dandruff and/or Seborrheic Dermatitis 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 Dermatitis 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:



John Amico

J O H N A M I C O

MEDACLEAR
SHAMPOO
SCALP & SKIN
TREATMENT

MEDICATED FORMULA

TREATMENT FOR:

- FLAKING SCALP & SKIN
- OILY SCALP
- ITCHY SCALP

SYMPTOM RELIEF FOR:

- SEBORRHEIC
- DERMATITIS AND
- PSORIASIS

8.0 FL OZ

Drug Facts

Active Ingredient	Purpose
1.5% Zinc Pyrithione	Antidandruff and AntiSeborrheic Dermatitis

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if you have seborrheic dermatitis that covers a large area of the body. On children under 2 years of age.

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Directions
Wet hair, massage onto scalp, rinse, repeat if desired. For maximum dandruff control, use every time you shampoo. For best results use at least twice a week, or as directed by a doctor.

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

Questions? 1-800-JohnAmico

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

8oz Label

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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 MONOHYDRATE (UNII: 2968PHW8QP)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
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	Business Operations
Continental Manufacturing Chemist, Inc.		005278007	MANUFACTURE(51290-011)