

**AMERICAN CREW ANTI-DANDRUFF PLUS SEBUM CONTROL- pyrrithione zinc shampoo
Colomer USA, Ltd.**

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.

American Crew® Anti-Dandruff + Sebum Control Shampoo

Drug Facts

Active Ingredients

Pyrrithione Zinc 1%

Purpose

Anti-dandruff

Uses

Controls itching & flaking due to dandruff.

Warnings

- For external use only.
- Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.
- If condition worsens or does not improve after regular use of this product as directed, consult a physician.
- Consult a physician prior to use in children under 2 years of age.
- KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Wet hair thoroughly.
- Massage a small amount of shampoo evenly into scalp and leave on for a few minutes.
- Rinse well.
- For best results use at least twice a week or as directed by a physician.

Inactive Ingredients

Aqua (Water) (Eau), Sodium Laureth Sulfate, Acrylates Copolymer, Cocamidopropyl Betaine, Glycerin, PEG-12 Dimethicone, Di-PPG-2 Myreth-10 Adipate, Triethanolamine, Hydroxyethylcellulose, Propylene Glycol, Sodium Chloride, Polyquaternium-7, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Mentha Piperita (Peppermint) Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract, Salvia Officinalis (Sage) Leaf Extract, Sodium Acetate, Parfum (Fragrance), Limonene, Phenoxyethanol, Ethylparaben, Methylparaben, Methylchloroisothiazolinone, Methylisothiazolinone

PRINCIPAL DISPLAY PANEL - 250mL Bottle Label

AMERICAN

CREW®
TRICHOLOGY

Official Supplier to Men™

ANTI-DANDRUFF +
SEBUM CONTROL
SHAMPOO

Anti-dandruff + sebum
control shampoo with
conditioning properties

250mL e / 8.4 Fl. Oz.

A M E R I C A N

CREW[®]

T R I C H O L O G Y

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Shampooing-soin
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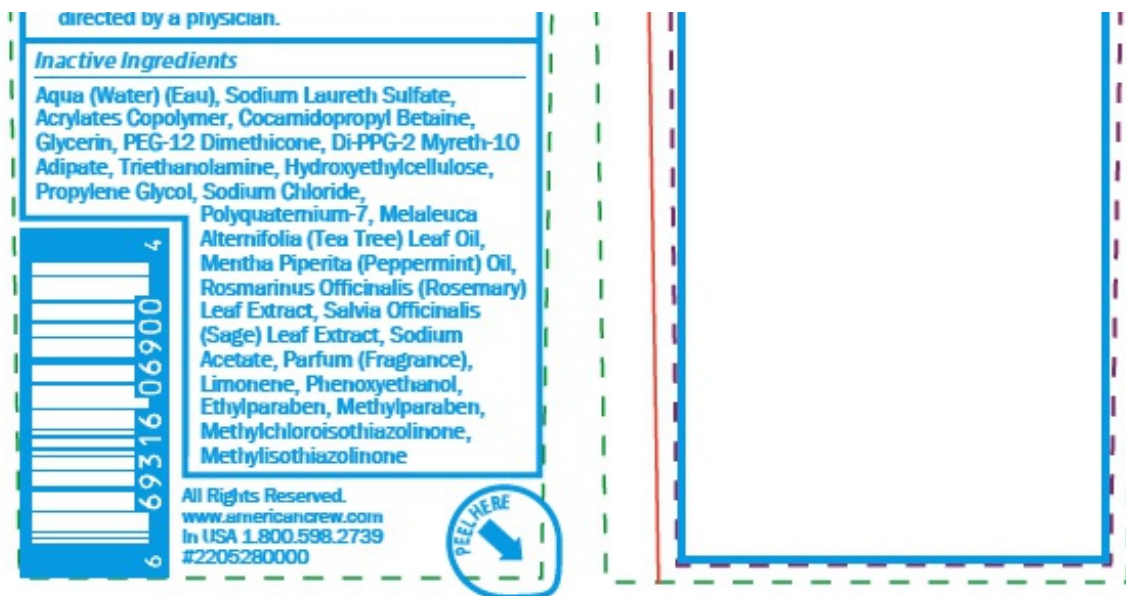
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Cleansing and conditioning shampoo to soothe and refresh hair and scalp. Pyrithione Zinc, vitamins and minerals help prevent itching, flaking and oil buildup.

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AMERICAN CREW ANTI-DANDRUFF PLUS SEBUM CONTROL

pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42743-4700
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Pyrithione Zinc (UNII: R953O2RHZ5) (Pyrithione Zinc - UNII:R953O2RHZ5)	Pyrithione Zinc	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)	
DI-PPG-2 MYRETH-10 ADIPATE (UNII: 4IN301M0KJ)	
TROLAMINE (UNII: 9O3K93S3TK)	
HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 160000 MW) (UNII: 0L414VCS5Y)	
TEA TREE OIL (UNII: VIF565UC2G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
ROSEMARY (UNII: IJ67X351P9)	
SAGE (UNII: 065C5D077J)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYL PARABEN (UNII: 14255EXE39)	
METHYL PARABEN (UNII: A2I8C7H9T)	
METHYL CHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42743-4700-1	250 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part358H	08/31/2013	

Labeler - Colomer USA, Ltd. (137750993)

Establishment

Name	Address	ID/FEI	Business Operations
Tri Tech Laboratories		792844680	MANUFACTURE(42743-4700) , PACK(42743-4700)