# ESIKA MEN EFFECTIVE CONTROL- pyrithione zinc liquid Ventura Corporation (San Juan, P.R)

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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ēs ika MEN s hampoo Effective Control

**Drug Facts** 

### **Active Ingredients**

Pyrithione Zinc (0.36%)

#### **Purpose**

Antidandruff

#### Uses

• Helps stop irritation and flaking associated with dandruff:

### **Warnings**

- for external use only.
- avoid contact with eyes. If contacts occurs, rinse eyes thoroughly with water.
- if condition worsens or does not improve after regular use of this product as directed, consult a doctor (or physician).
- **Keep out of reach of children**. If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

• For best results, use at least 2 times a week or as directed by a doctor (or physician).

#### Other information

• Ask a doctor before use if you have seborrheic dermatitis that covers a large area of the body.

#### **Inactive ingredients**

Aqua (water), sodium laureth sulfate, cocamidopropyl betaine, cocamide dea, dimethiconol, hydrolyzed soy protein, lauryl glucoside, coco-glucoside, glyceryl oleate, sodium chloride, hydrolyzed wheat protein, acrylates/c10-30 alkyl acrylate crosspolymer, triethanolamine, fragrance, guar hydroxypropyltrimonium chloride, glycol distearate, tea-dodecylbenzenesulfonate, tetrasodium edta, ci 77891 (titanium dioxide), cocamide mea, laureth-10, magnesium nitrate, citric acid, zinc chloride, butylene glycol, ci 19140 (yellow 5), methylchloroisothiazolinone, magnesium chloride, ppg-26-buteth-26, methylisothiazolinone, peg-40 hydrogenated castor oil, ci 42090 (blue 1), ci 14700 (red 4),

apigenin, oleanolic acid, biotinoyl tripeptide-1.

## PRINCIPAL DISPLAY PANEL - 300 ml Bottle Label

**MEN** 

shampoo **Effective Control** 

For all types of hair

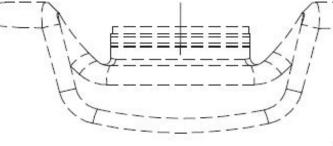
- > controls symptoms of dandruff with pyrithione zinc
  > Strengthens debilitated hair

ēsika 300 ml e (10.1 fl.oz)



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ēSIK∂ 300 mle(10.1 fl.oz)



Esika Men provides effective nelp for the 2 principal problems affecting masculine hair symptoms of dandruff and the weakening of the hair. Its Capillar Tech acts with Zinc Pyritionate (effective anti-dandruff agent) and with wheat and soybean natural micro-proteins which reinforce the debilitated hair.

## **Drug Facts**

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## Uses

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## Directions

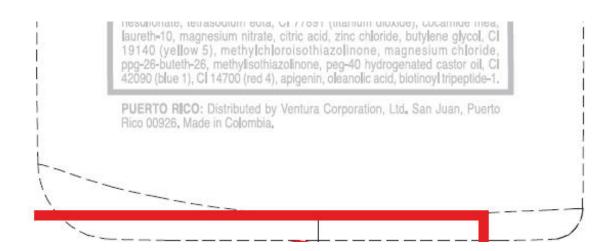
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## Other information

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## Inactive ingredients

Aqua (water), sodium laureth sulfate, cocamidopropyl betaine, cocamide dea, dimethiconol, hydrolyzed soy protein, lauryl glucoside, coco-glucoside, glyceryl oleate, sodium chloride, hydrolyzed wheat protein, acrylates/c10-30 alkyl acrylate crosspolymer, triethanolamine, parfum (fragrance), guarhydroxypropyltrimonium chloride, glycol disterate, tea-dodecylbenze-



## ESIKA MEN EFFECTIVE CONTROL

pyrithione zinc liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-341
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Pyrithione Zinc (UNII: R953O2RHZ5) (Pyrithione Zinc - UNII:R953O2RHZ5)	Pyrithione Zinc	0.0036 mg in 1 mL	

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
sodium laureth sulfate (UNII: BPV390UAP0)	
cocamidopropyl betaine (UNII: 5OCF3O11KX)	
coco diethanolamide (UNII: 92005F972D)	
lauryl glucoside (UNII: 76LN7P7UCU)	
coco glucoside (UNII: ICS790225B)	
glyceryl monooleate (UNII: 4PC054V79P)	
sodium chloride (UNII: 451W47IQ8X)	
trolamine (UNII: 9O3K93S3TK)	
glycol distearate (UNII: 13W7MDN21W)	
tea-dodecylbenzenesulfonate (UNII: 8 HM7ZD48 HN)	
edetate sodium (UNII: MP1J8420LU)	
titanium dioxide (UNII: 15FIX9 V2JP)	
coco monoethanolamide (UNII: C80684146D)	
laureth-10 (UNII: BD7AST04GA)	
magnesium nitrate (UNII: 77CBG3UN78)	
citric acid monohydrate (UNII: 2968PHW8QP)	
zinc chloride (UNII: 86Q357L16B)	
butylene glycol (UNII: 3XUS85K0RA)	
fd&c yellow no. 5 (UNII: I753WB2F1M)	

methylchloroisothiazolinone (UNII: DEL7T5QRPN)		
magnesium chloride (UNII: 02F3473H9O)		
methylisothiazolinone (UNII: 229 D0 E1QFA)		
polyoxyl 40 hydrogenated castor oil (UNII: 7YC686GQ8F)		
fd&c blue no. 1 (UNII: H3R47K3TBD)		
fd&c red no. 4 (UNII: X3W0 AM1JLX)		
oleanolic acid (UNII: 6SMK8R7TGJ)		

]	Packaging			
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-341-01	300 mL in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part358H	05/17/2011		

# Labeler - Ventura Corporation (San Juan, P.R) (602751344)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bel Star S.A. (Colombia)		880160197	MANUFACTURE	

Revised: 5/2011 Ventura Corporation (San Juan, P.R)