

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.

ē sika
MEN
shampoo
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)



MEN



shampoo

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ēsika
300 ml e (10.1 fl.oz)

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

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tris(trimethylsilyl)phosphite, tetrasodium edta, CI 77051 (titanium dioxide), cocamide tma, 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.

PUERTO RICO: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926. Made in Colombia.

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

Inactive Ingredients

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: 8HM7ZD48HN)	
edetate sodium (UNII: MP1J8420LU)	
titanium dioxide (UNII: 15FIX9V2JP)	
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: 229D0E1QFA)	
polyoxyl 40 hydrogenated castor oil (UNII: 7YC686GQ8F)	
fd&c blue no. 1 (UNII: H3R47K3TBD)	
fd&c red no. 4 (UNII: X3W0AMJLX)	
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)