ESIKA VITAL WITH ACTIVE Z 2-IN-1 DANDRUFF 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.

ēsika Vital WITH ACTIVE-Z 2 in 1 DANDRUFF CONTROL SHAMPOO + HAIR CONDITIONER

Drug Facts

Active Ingredients

Pyrithione Zinc (0.34%)

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

- Apply shampoo to wet hair. Massage until foaming. Rinse with water to remove all hair shampoo.
 Repeat if necessary.
- 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, dimethicone, cocamide mipa, cetyl alcohol, sodium chloride, glycol distearate, parfum (fragrance), polyquaternium-7, guar

hydroxypropyltrimonium chloride, citric acid, magnesium nitrate, aloe barbadensis leaf juice, hydrolyzed soy protein, hydrolyzed wheat protein, soluble collagen, zinc chloride, zinc pca, methylchloroisothiazolinone, magnesium chloride, methylisothiazolinone.

PRINCIPAL DISPLAY PANEL - 400 ml Bottle Label

Vital

WITH ACTIVE-Z

2 in 1

DANDRUFF CONTROL

SHAMPOO + HAIR CONDITIONER

FOR CONTROLLING DANDRUFF WITH PYRITHIONE ZINC

ēsika

400 ml e (13.5 fl.oz.)



ESIKA VITAL WITH ACTIVE Z 2-IN-1 DANDRUFF CONTROL

pyrithione zinc liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-353
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Pyrithione Zinc (UNII: R953O2RHZ5) (Pyrithione Zinc - UNII:R953O2RHZ5)	Pyrithione Zinc	0.0034 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
sodium laureth sulfate (UNII: BPV390UAP0)	
cocamidopropyl betaine (UNII: 5OCF3O11KX)	
dimethicone (UNII: 92RU3N3Y1O)	
cetyl alcohol (UNII: 936JST6JCN)	
sodium chloride (UNII: 451W47IQ8X)	
glycol distearate (UNII: 13W7MDN21W)	
citric acid monohydrate (UNII: 2968PHW8QP)	
magnesium nitrate (UNII: 77CBG3UN78)	
aloe vera leaf (UNII: ZY8 1Z8 3H0 X)	
zinc chloride (UNII: 86Q357L16B)	
zinc pidolate (UNII: C32PQ86DH4)	
methylchloroisothiazolinone (UNII: DEL7T5QRPN)	
magnesium chloride (UNII: 02F3473H9O)	
methylisothiazolinone (UNII: 229 D0 E1QFA)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-353-01	400 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)