

**ESIKA MEN MAXIMUM STRENGTH- pyrithione zinc liquid**  
**Ventura International 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.*

-----

**ésika Men Shampoo Maximum Strength**

***Drug Facts***

**Active Ingredient**

ZINC PYRITHIONE 0.528 %

**Purpose**

Antidandruff shampoo

**Uses**

Reduces the symptoms of dandruff

**Warnings**

**For external use only**

Avoid contact with the 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 doctor

**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 twice a week or as directed by a doctor.

**Inactive ingredients**

WATER, SODIUM LAURETH SULFATE, COCAMIDE DEA, COCAMIDOPROPYL BETAINE, DIMETHICONOL, GLYCOL DISTEARATE, HYDROLYZED SOY PROTEIN, SODIUM CHLORIDE, FRAGRANCE, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, TRIETHANOLAMINE, GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, COCO-GLUCOSIDE, HYDROLYZED WHEAT PROTEIN, TEA-DODECYLBENZENESULFONATE, GLYCERYL OLEATE, GLYCERYL STEARATE, CI 77891 (TITANIUM DIOXIDE ), MAGNESIUM NITRATE, CITRIC ACID, HYDROLYZED RICE PROTEIN, ZINC CHLORIDE, BUTYLENE GLYCOL, CI 19140 (YELLOW 5), PANTHENOL, HYDROLYZED CORN PROTEIN, MENTHYL PCA, METHYLCHLOROISOTHIAZOLINONE, MENTHA AQUATICA LEAF EXTRACT, PROPYLENE GLYCOL, MAGNESIUM CHLORIDE, SACCHAROMYCES/MAGNESIUM FERMENT, CI 14700 (RED 4), PPG-26-BUTETH-26, METHYLISOTHIAZOLINONE, PEG-40 HYDROGENATED CASTOR OIL, MENTHOL, DIPROPYLENE GLYCOL, SACCHAROMYCES/IRON FERMENT, SACCHAROMYCES/COPPER FERMENT, SACCHAROMYCES/SILICON FERMENT, SACCHAROMYCES/ZINC FERMENT, CI 42090 (BLUE 1), APIGENIN, BIOTINOYL TRIPEPTIDE-1, OLEANOLIC ACID

**Puerto Rico:** Distributed by Ventura Corporation Ltd., San Juan, Puerto Rico 00924.

**PRINCIPAL DISPLAY PANEL - 300 ml Bottle Label**

**MEN**

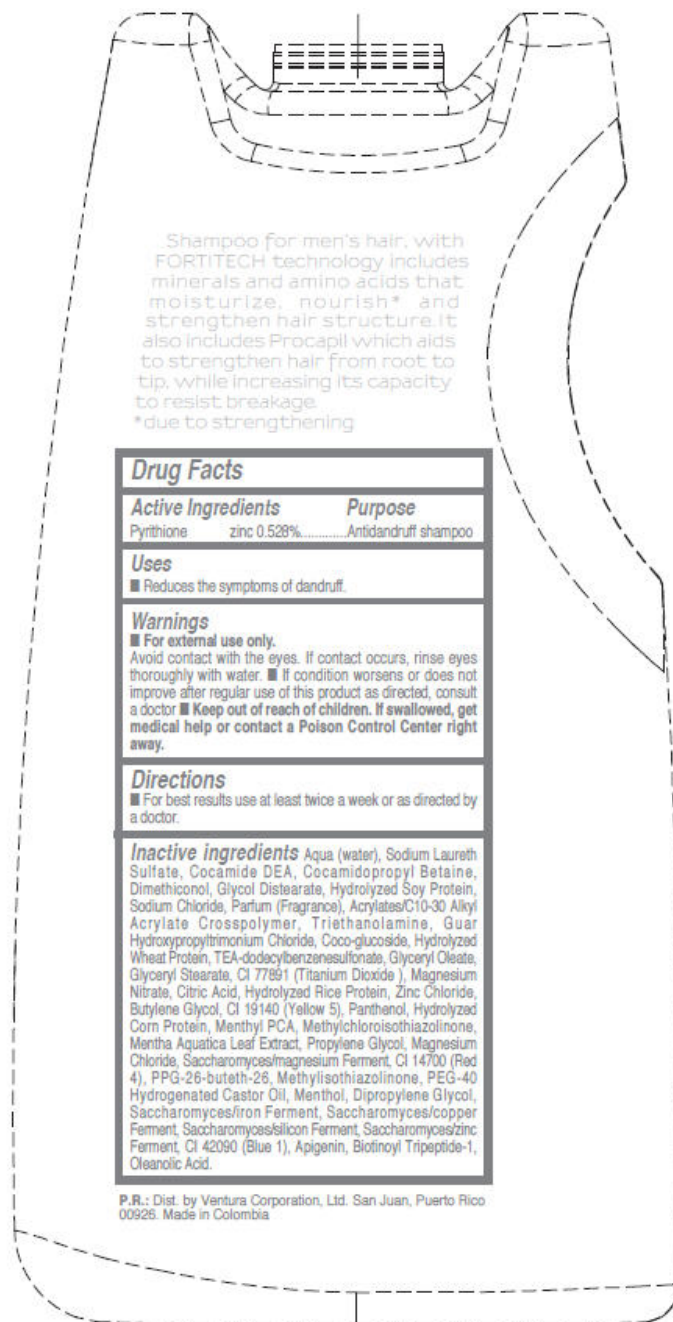
**shampoo**

**Maximum Strength**

- > Nourishes\* and moisturizes hair
- > Prevents dandruff
- > Provides maximum cleaning  
\*due to strengthening

**ésika**

300 ml e (10.1 fl.oz)



## ESIKA MEN MAXIMUM STRENGTH

pyrithione zinc liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:14783-449
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	0.00528 g in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
CO CO DIETHANOLAMIDE (UNII: 92005F972D)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TROLAMINE (UNII: 9O3K93S3TK)	
CO CO GLUCOSIDE (UNII: ICS790225B)	
TEA-DO DECYLBENZENESULFONATE (UNII: 8HM7ZD48HN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM NITRATE (UNII: 77CBG3UN78)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ZINC CHLORIDE (UNII: 86Q357L16B)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
PANTHENOL (UNII: WV9CM0O67Z)	
MENTHYL PYRROLIDONE CARBOXYLATE, (-),DL- (UNII: 8P18J856U2)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
MENTHA AQUATICA LEAF (UNII: 5M106ME6PT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
FD&C RED NO. 4 (UNII: X3W0AMJLX)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
MENTHOL (UNII: L7T10EIP3A)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
APIGENIN (UNII: 7V515PI7F6)	
BIO TINO YL TRIPEPTIDE-1 (UNII: O6380721VA)	
OLEANOLIC ACID (UNII: 6SMK8R7TGJ)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-449-01	300 mL in 1 BOTTLE, PLASTIC		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part358H	01/24/2012	

**Labeler** - Ventura International Ltd (603192787)

**Establishment**

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

Revised: 1/2012

Ventura International Ltd