

ESIKA MEN MAXIMUM STRENGTH- pyrithione zinc liquid
Ventura Corporation 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.

ESIKA 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

MEN

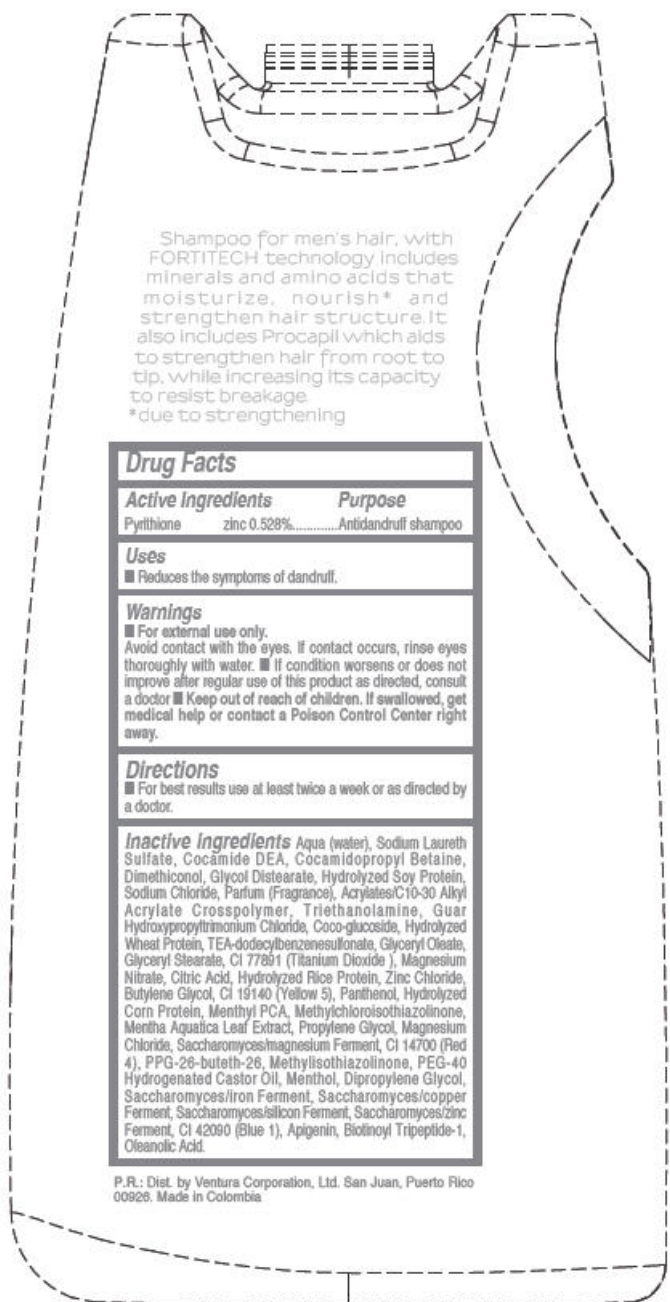
shampoo

Maximum Strength

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

ēsika

300 ml e (10.1 fl.oz)



ESIKA MEN MAXIMUM STRENGTH

pyrithione zinc liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-154
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)		PYRITHIONE ZINC	0.00528 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TROLAMINE (UNII: 9O3K93S3TK)	
COCO 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: X3W0AM1JLX)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
MENTHOL (UNII: L7T10EIP3A)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
APIGENIN (UNII: 7V515PI7F6)	
BIO TINOYL TRIPEPTIDE-1 (UNII: O6380721VA)	
OLEANOLIC ACID (UNII: 6SMK8R7TGJ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-154-01	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 Corporation Ltd (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-154)

Revised: 1/2012

Ventura Corporation Ltd