

ESIKA MEN 2 EN 1 ANTIDANDRUFF MULTI-ACTION- pyrrithione 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.

ÉSIKA MEN 2 EN 1 ANTIDANDRUFF SHAMPOO MULTI-ACTION

Drug Facts

Active Ingredient

PYRITHIONE ZINC 0.5%

Purpose

Antidandruff

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, HYDROLYZED SOY PROTEIN, SODIUM CHLORIDE, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, GLYCOL DISTEARATE, TRIETHANOLAMINE, GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, FRAGRANCE, COCO-GLUCOSIDE, HYDROLYZED RICE PROTEIN, TEA-DODECYLBENZENESULFONATE, HYDROLYZED WHEAT PROTEIN, CITRIC ACID, PROPYLENE GLYCOL, TITANIUM DIOXIDE, GLYCERYL OLEATE, GLYCERYL STEARATE, MAGNESIUM NITRATE, ZINC CHLORIDE, BUTYLENE GLYCOL, BAMBUSA ARUNDINACEA LEAF EXTRACT, BLUE 1, PANTHENOL, YELLOW 5, METHYLCHLOROISOTHIAZOLINONE, MAGNESIUM CHLORIDE, PPG-26-BUTETH-26, METHYLISOTHIAZOLINONE, PEG-40 HYDROGENATED CASTOR OIL, MENTHYL PCA, MENTHOL, DIPROPYLENE GLYCOL, APIGENIN, RED 33, OLEANOLIC ACID, BIOTINOYL TRIPEPTIDE-1, HEXYL CINNAMAL, LINALOOL, BUTYLPHENYL METHYLPROPIONAL, CITRONELLOL.

Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926.

PRINCIPAL DISPLAY PANEL - 300 ml Bottle Label

MEN

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antidandruff shampoo

Multi-action

- > **maximum brilliance and softness**
- > controls symptoms of dandruff
with pyrithione zinc
- > hair can be combed more easily

ésika

300 ml e (10.1 fl.oz.)



ESIKA MEN 2 EN 1 ANTIDANDRUFF MULTI-ACTION

pyrrithione zinc liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-751
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Pyrrithione Zinc (UNII: R953O2RHZ5) (Pyrrithione Zinc - UNII:R953O2RHZ5)	Pyrrithione Zinc	0.05 g in 1 mL

Inactive Ingredients

	Ingredient Name	Strength
	WATER (UNII: 059QF0KO0R)	
	SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
	CO CO DIETHANOLAMIDE (UNII: 92005F972D)	
	CO CAMIDO PROPYL BETAINE (UNII: 5OCF3011KX)	
	HYDROLYZED SO Y PROTEIN (ENZYMATIC; 2000 MW) (UNII: 1394NXB9L6)	
	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
	CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
	GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
	TROLAMINE (UNII: 9O3K93S3TK)	
	GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
	CO CO GLUCO SIDE (UNII: ICS790225B)	
	TRIETHANOLAMINE DODECYLBENZENESULFONATE (UNII: 8HM7ZD48HN)	
	HYDROLYZED WHEAT PROTEIN (ENZYMATIC; 3000 MW) (UNII: J2S07SB0YL)	
	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
	GLYCERYL OLEATE (UNII: 4PC054V79P)	
	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
	MAGNESIUM NITRATE (UNII: 77CBG3UN78)	
	ZINC CHLORIDE (UNII: 86Q357L16B)	
	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
	BAMBUSA BAMBOS LEAF (UNII: HW86D1FGSS)	
	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
	PANTHENOL (UNII: WV9CM0O67Z)	
	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
	METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
	MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
	PPG-26-BUTETH-26 (UNII: 2I1K6TZ4P)	
	METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
	POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
	MENTHYL DL-PYRROLIDONECARBOXYLATE (UNII: 8P18J856U2)	
	MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
	DIPROPYLENE GLYCOL (UNII: E107L85C40)	
	APIGENIN (UNII: 7V515PI7F6)	
	D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
	OLEANOLIC ACID (UNII: 6SMK8R7TGJ)	
	BIO TINO YL TRIPEPTIDE-1 (UNII: O6380721VA)	
	.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
	LINALOOL, (+/-)- (UNII: D81QY6I88E)	
	BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
	.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:13537-751-01	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/17/2015	
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	08/17/2015	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-751)

Revised: 8/2016

Ventura Corporation LTD