

LBEL HOMME ANTIDANDRUFF- pyrithione zinc shampoo
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.

L'BEL HOMME
Antidandruff Shampoo

Drug Facts

Active Ingredient

ZINC PYRITHIONE 0.336 %

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

AQUA (WATER), SODIUM LAURETH SULFATE , COCAMIDE DEA, COCAMIDOPROPYL BETAINE, DIMETHICONOL, SODIUM CHLORIDE, GLYCOL DISTEARATE, PARFUM (FRAGRANCE), GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, TRIETHANOLAMINE, BUTYLENE GLYCOL, HYDROXYPROPYL METHYLCELLULOSE, COCO-GLUCOSIDE, TEA-DODECYLBENZENESULFONATE, HYDROLYZED SOY PROTEIN, HYDROLYZED WHEAT PROTEIN, GLYCERYL STEARATE, GLYCERYL OLEATE, MAGNESIUM NITRATE, MENTHYL PCA, ZINC CHLORIDE, GLYCERIN, PPG-26-BUTETH-26, PEG-40 HYDROGENATED CASTOR OIL, MENTHOL, DIPROPYLENE GLYCOL, METHYLCHLOROISOTHIAZOLINONE, MAGNESIUM CHLORIDE, METHYLISOTHIAZOLINONE, APIGENIN, OLEANOLIC ACID, MORINGA PTERYGOSPERMA SEED EXTRACT, BIOTINOYL TRIPEPTIDE-1

US: Distributed by Ventura International Ltd. San Francisco, CA 94111. Made in Colombia.

PRINCIPAL DISPLAY PANEL - 250 ml Bottle

L'BEL HOMME

Antidandruff Shampoo

> fortified hair

> daily use

L'BEL

250 ml e (8.4 fl.oz.)



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Directions

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Inactive ingredients Aqua (Water), Sodium Laureth Sulfate, Cocamide Dea, Cocamidopropyl Betaine, Dimethiconol, Sodium Chloride, Glycol Distearate, Parfum (Fragrance), Guar Hydroxypropyltrimonium Chloride, Acrylates/c10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Butylene Glycol, Hydroxypropyl Methylcellulose, Coco-glucoside, Tea-dodecylbenzenesulfonate, Hydrolyzed Soy Protein, Hydrolyzed Wheat Protein, Glyceryl Stearate, Glyceryl Oleate, Magnesium Nitrate, Menthyl Pca, Zinc Chloride, Glycerin, Ppg-26-buteth-26, Peg-40 Hydrogenated Castor Oil, Menthol, Dipropylene Glycol, Methylchloroisothiazolinone, Magnesium Chloride, Methylisothiazolinone, Apigenin, Oleoanolic Acid, Moringa Pterygosperma Seed Extract, Biotinoyl Tripeptide-1.

P.R.: Distributed by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926. Made in Colombia. US: Distributed by Ventura International Ltd. San Francisco, CA 94111. Made in Colombia.

pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-436
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Pyrithione Zinc (UNII: R953O2RHZ5) (Pyrrithione Zinc - UNII:R953O2RHZ5)	Pyrrithione Zinc	0.00336 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Sodium Laureth Sulfate (UNII: BPV390UAP0)	
Coco Diethanolamide (UNII: 92005F972D)	
Cocamidopropyl Betaine (UNII: 5OCF3011KX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
Trolamine (UNII: 9O3K93S3TK)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Coco Glucoside (UNII: ICS790225B)	
Tea-dodecylbenzenesulfonate (UNII: 8HM7ZD48HN)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Magnesium Nitrate (UNII: 77CBG3UN78)	
Menthyl Pyrrolidone Carboxylate, (-),DI- (UNII: 8P18J856U2)	
Zinc Chloride (UNII: 86Q357L16B)	
Glycerin (UNII: PDC6A3C0OX)	
Polyoxyl 40 Hydrogenated Castor Oil (UNII: 7YC686GQ8F)	
Menthol (UNII: L7T10EIP3A)	
Dipropylene Glycol (UNII: E107L85C40)	
Methylchloroisothiazolinone (UNII: DEL7T5QRPN)	
Magnesium Chloride (UNII: 02F3473H9O)	
Methylisothiazolinone (UNII: 229D0E1QFA)	
Apigenin (UNII: 7V515PI7F6)	
Oleanolic Acid (UNII: 6SMK8R7TGJ)	
Moringa Oleifera Seed (UNII: TIX5482832)	
Biotinoyl Tripeptide-1 (UNII: O6380721VA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-436-01	250 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part358H	01/20/2012	

Labeler - Ventura International Ltd (603192787)

Establishment

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

Revised: 1/2012

Ventura International Ltd