

**LBEL DRY EFFECT 48 ANTIPERSPIRANT DEODORANT ROLL-ON- aluminum
sesquichlorohydrate emulsion
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.

L'BEL DRY EFFECT 48 ANTIPERSPIRANT DEODORANT ROLL-ON

Drug Facts

Active Ingredient

Aluminum sesquichlorohydrate 18.00%

Purpose

Antiperspirant

Uses

- Reduces underarm perspiration

Warnings

For external use only

Do not use on broken skin

Ask a doctor before use if you have Kidney disease

Stop use and ask a doctor if rash or irritation occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply to underarms only.

Inactive ingredients

WATER, STEARETH-2, STEARETH-21, PPG-15 STEARYL ETHER, COCO-CAPRYLATE, DICAPRYLYL CARBONATE, FRAGRANCE, TRICLOSAN, POLYVINYL ALCOHOL, METHYLPARABEN, BISABOLOC, PROPYLENE CARBONATE, BENZALKONIUM CHLORIDE, PEG-20 CASTOR OIL, BHT, ACRYLATES/C12-22 ALKYL METHACRYLATE COPOLYMER, ALCOHOL DENAT., PROPYLENE GLYCOL, STEARALKONIUM HECTORITE, MENTHA PIPERITA (PEPPERMINT) LEAF EXTRACT, THYMUS VULGARIS (THYME) EXTRACT, HYDROLYZED SILK, TETRASODIUM EDTA, ORIGANUM VULGARE LEAF EXTRACT, ZEA MAYS (CORN) OIL, CALCIUM PANTOTHENATE, INOSITOL, RETINOL, ROSMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT, ROSA MOSCHATA SEED OIL, LAVANDULA ANGUSTIFOLIA (LAVENDER) FLOWER EXTRACT, CINNAMOMUM ZEYLANICUM BARK EXTRACT, HYDRASTIS CANADENSIS (GOLDENSEAL) ROOT EXTRACT, OLEA EUROPAEA (OLIVE) LEAF EXTRACT, CITRUS LIMON (LEMON) PEEL EXTRACT, CYMBOPOGON CITRATUS EXTRACT, HYDROLYZED CORN STARCH, HYDROLYZED CORN STARCH

OCTENYLSUCCINATE, MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF, ZEA MAYS (CORN) STARCH, BIOTIN, TOCOPHERYL ACETATE, HEXYL CINNAMAL, BUTYLPHENYL METHYLPROPIONAL, HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE, LINALOOL, ALPHA-ISOMETHYL IONONE, CITRONELLOL, COUMARIN.

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

PRINCIPAL DISPLAY PANEL - 50 ml Bottle Label

antiperspirant deodorant
roll on

L'BEL
dryeffect
48

50 ml e (1.7 fl.oz.)

cuidado y suavidad

antiperspirant deodorant
roll on

L'BEL
dryeffect
48

50 ml e (1.7 fl.oz.)

Drug Facts	Active Ingredients Purpose
	Aluminum sesquichlorohydrate (18.00%).....Antiperspirant
Uses	<ul style="list-style-type: none"> ■ Reduces underarm perspiration. ■ All day extra effective protection
Warnings	<ul style="list-style-type: none"> ■ For external use only. ■ Do not use on broken skin. ■ Ask a doctor before use if you have kidney disease. ■ Stop use if rash and irritation occurs. ■ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions	<ul style="list-style-type: none"> ■ Apply to underarms only.

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Drug Facts
(continued)

Inactive Ingredients water, steareth-2, steareth-21, ppg-15 stearyl ether, coco-caprylate, dicaprylyl carbonate, fragrance, triclosan, polyvinyl alcohol, methylparaben, bisabolol, propylene carbonate, benzalkonium chloride, peg-20 castor oil, bht, acrylates/c12-22 alkyl methacrylate copolymer, alcohol denat., propylene glycol, stearylalkonium hectorite, mentha piperita (peppermint) leaf extract, thymus vulgaris (thyme) extract, hydrolyzed silk, tetrasodium edta, organum vulgare leaf extract, zea mays (corn) oil, calcium pantothenate, inositol, retinol, rosmarinus officinalis (rosemary) leaf extract, rosa moschata seed oil, lavandula angustifolia (lavender) flower extract, cinnamomum zeylanicum bark extract, hydrastis canadensis (goldenseal) root extract, olea europaea (olive) leaf extract, citrus limon (lemon) peel extract, cymbopogon citraus extract, hydrolyzed corn starch, hydrolyzed corn starch octenylsuccinate, melaleuca alternifolia (tea tree) leaf, zea mays (corn) starch, biotin, tocopheryl acetate, hexyl cinnamal, butylphenyl methylpropional, hydroxyisohexyl 3-cyclohexene carboxaldehyde, linalool, alpha-isomethyl ionone, citronellol, coumarin.

• DERMATOLOGICALLY TESTED FOR GENTLENESS.
 • HYPOALLERGENIC
 PUERTO RICO: Dist. by Ventura Corp. Ltd., San Juan, Puerto Rico
 00926, Miami, Florida, U.S.A.
 U.S.A.: Dist. by Ventura Int. Ltd., DSH Distrib
 USA, Miami, FL 33128 Made in California

LBEL DRY EFFECT 48 ANTIPERSPIRANT DEODORANT ROLL-ON

aluminum sesquichlorohydrate emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-956
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM SESQUICHLORO HYDRATE (UNII: UCN889409V) (ALUMINUM SESQUICHLORO HYDRATE - UNII:UCN889409V)	ALUMINUM SESQUICHLORO HYDRATE	0.18 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-21 (UNII: 53J3F32P58)	
PPG-15 STEARYL ETHER (UNII: 1II18XLS1L)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
TRICLOSAN (UNII: 4NM5039Y5X)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
LEVOMENOL (UNII: 24WE03BX2T)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
THYME (UNII: CW6570BU4N)	
EDETATE SODIUM (UNII: MP1J8420LU)	
OREGANO (UNII: 0E5AT8T16U)	
CORN OIL (UNII: 8470G57WFM)	
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)	
INOSITOL (UNII: 4L6452S749)	
RETINOL (UNII: G2SH0XKK91)	
ROSEMARY (UNII: IJ67X351P9)	
ROSA MOSCHATA SEED OIL (UNII: T031ZE559T)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	
CINNAMON BARK OIL (UNII: XE54U569EC)	
GOLDENSEAL (UNII: ZW3Z11D0JV)	
OLEA EUROPAEA LEAF (UNII: MJ95C30H47)	
LEMON PEEL (UNII: 72O054U628)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
STARCH, CORN (UNII: O8232NY3SJ)	
BIOTIN (UNII: 6SO6U10H04)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
COUMARIN (UNII: A4VZ22K1WT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-956-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/05/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part350	07/05/2016	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-956)

Revised: 7/2016

Ventura Corporation LTD