

**ESIKA WINNER BLACK ANTIPERSPIRANT ROLL-ON DEODORANT- 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.

ESIKA WINNER BLACK ANTIPERSPIRANT ROLL-ON DEODORANT

Drug Facts

Active Ingredient

ALUMINUM SESQUICHLOROXYDRATE 13.60 %

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 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, PPG-15 STEARYL ETHER, STEARETH-21, FRAGRANCE, DICAPRYLYL CARBONATE, CYCLOPENTASILOXANE, BENZYL ALCOHOL, TRICLOSAN, CYCLOHEXASILOXANE, HYDROXYACETOPHENONE, TETRASODIUM EDTA, BISABOLOL, HEXYL CINNAMAL, LINALOOL, BENZYL SALICYLATE, d-LIMONENE, COUMARIN.

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

PRINCIPAL DISPLAY PANEL - 50 ml Bottle Label

**WINNER
BLACK**

ANTIPERSPIRANT
ROLL-ON DEODORANT

ésika

50 ml e (1.6 fl.oz.)



ESIKA WINNER BLACK ANTIPERSPIRANT ROLL-ON DEODORANT

aluminum sesquichlorohydrate emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-850
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM SESQUICHLORO HYDRATE (UNII: UCN889409 V) (ALUMINUM SESQUICHLORO HYDRATE - UNII:UCN889409 V)	ALUMINUM SESQUICHLORO HYDRATE	0.136 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
STEARETH-2 (UNII: V56DFE46J5)	
PPG-15 STEARYL ETHER (UNII: 1II18 XLS 1L)	
STEARETH-21 (UNII: 53J3F32P58)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
TRICLOSAN (UNII: 4NM5039 Y5X)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
EDETATE SODIUM (UNII: MP1J8420LU)	
LEVOMENOL (UNII: 24WE03BX2T)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

COUMARIN (UNII: A4VZ22K1WT)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-850-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/09/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part350	12/09/2016	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-850)

Revised: 12/2016

Ventura Corporation LTD