

**CYZONE NITRO DESODORANTE ANTITRANSPIRANTE ROLL-ON FM- 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.

CY°ZONE NITRO DESODORANTE ANTITRANSPIRANTE ROLL-ON FM

Drug Facts

Active Ingredient

Aluminum sesquichlorohydrate 13.6 %

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, PPG-15 STEARYL ETHER, STEARETH-21, FRAGRANCE, DICAPRYLYL CARBONATE, CYCLOPENTASILOXANE, BENZYL ALCOHOL, TRICLOSAN, CYCLOHEXASILOXANE, TETRASODIUM EDTA, BISABOLOL, LINALOOL, d-LIMONENE, HEXYL CINNAMAL, BENZYL SALICYLATE, BUTYLPHENYL METHYLPROPIONAL, COUMARIN, CITRONELLOL, EUGENOL, CITRAL, ALPHA-ISOMETHYL IONONE, GERANIOL.

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

PRINCIPAL DISPLAY PANEL - 50 ml Bottle Label

NITRO

Desodorante **Antitranspirante** Roll On FM

cy°zone 50 ml e (1.7 fl.oz.)

NITRO

Desodorante **Antitranspirante** Roll On FM
cy^ozone 50 ml e (1.7 fl.oz.)

Controls excess perspiration and protects against odors, leaving a pleasant scent.

Información del medicamento

Ingredientes activos Propósito

Aluminum
sesquichlorohydrate...13.60% Antitranspirante

Uso ■ Reduce la transpiración de las axilas

Advertencias

Sólo para uso externo.

No usar en piel dañada o lastimada

Consulte con el doctor en caso de sufrir de enfermedad renal

Detenga su uso si sucede enrojecimiento

Mantener fuera del alcance de los niños.
Si es ingerido obtener ayuda médica o contactar al centro de Control de Envenenamiento inmediatamente

Instrucciones ■ Aplicar solamente en las axilas.

Inactive Ingredients

water, steareth-2, ppg-15 stearyl ether, steareth-21, fragrance, dicaprylyl carbonate, cyclopentasiloxane, benzyl alcohol, triclosan, cyclohexasiloxane, tetrasodium edta, bisabolol, linalool, d-limonene, hexyl cinnamal, benzyl salicylate, butylphenyl methylpropional, coumarin, citronellol, eugenol, citral, alpha-isomethyl ionone, geraniol

PUERTO RICO: Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926. Made in Colombia

CYZONE NITRO DESODORANTE ANTITRANSPIRANTE ROLL-ON FM

aluminum sesquichlorohydrate emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-963
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM SESQUICHLOROXYDRATE (UNII: UCN889409V) (ALUMINUM SESQUICHLOROXYDRATE - UNII:UCN889409V)	ALUMINUM SESQUICHLOROXYDRATE	0.136 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
STEARETH-2 (UNII: V56DFE46J5)	
PPG-15 STEARYL ETHER (UNII: 1H18XLS1L)	
STEARETH-21 (UNII: 53J3F32P58)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
TRICLOSAN (UNII: 4NM5039Y5X)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
EDETATE SODIUM (UNII: MP1J8420LU)	
LEVOMENOL (UNII: 24WE03BX2T)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
.ALPHA.-HEXYL CINNAMALDEHYDE (UNII: 7X6O37OK2I)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
COUMARIN (UNII: A4VZ22K1WT)	
.BETA.-CITRONELLOL, (R)- (UNII: P010UT964K)	
EUGENOL (UNII: 3T8H1794QW)	
CITRAL (UNII: T7EU009VPP)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
GERANIOL (UNII: L837108USY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-963-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/11/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part350	07/11/2016	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-963)

Revised: 7/2016

Ventura Corporation LTD