

STEFANO ROYAL- aluminum chlorohydrate liquid
TERESA CECENA DBA GENESIS

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.

ACTIVE INGREDIENT

Aluminium chlorhydrate

PURPOSE:

Antiperspirant

KEEP OUT THE REACH OF CHILDREN

USE:

Reduces underarm perspiration

FOR EXTERNAL USE ONLY

DIRECTION

APPLY UNDER ARM ONLY

SHAKE WELL BEFORE USE

DO NOT APPLY ON IRRITATED OR INJURED SKIN. DISCONTINUE USE IF YOU EXPERIENCE SOME IRRITATION, REDNESS OR DISCOMFORT

WATER, SOY OIL, STEARTH2, PPG-15 STEARYL ETHER, STEARETH-20,FRAGRANCE, CAPRYLYGLYCOL, TETRASODIUM, AND BHT

APPLY UNDER ARM

DO NOT APPLY ON IRRITATED OR INJURED SKIN, DISCONTINUE USE IF YOU EXPERIENCE SOME IRRITATION, REDNESS OR DISCOMFORT

DRUG FACTS

Active Ingredient

Aluminium Chlorhydrate

Purpose

Antiperspirant

Use: reduces underarm perspiration**Warnings:** For External Use Only. Not Apply On Irritated Or Injured Skin. Discontinue Use If You Experience Some Irritation, Redness Or Discomfort.**Keep Out Of Reach Of Children.****Directions:** Apply under arm only.
SHAKE WELL BEFORE USE.**Inactive Ingredients:** Water, Soy oil, steareth-2, PPG-15 stearyl ether, steareth-20, fragrance, capriliiglycol, tetrasodium EDTA and BHT.

MADE IN MEXICO: COLGATE PALMOLIVE S.A. DE C.V. PRESA LA ANGOSTURA NO. 225 COL. IRRIGACION MEXICO D.F. C.P. 11500. MADE BY MISION HILLS S.A. DE C.V. CARRETERA FEDERAL 57, KM 47 CARRETERA ENTRONCAL A SAN JOSE ITURBIDE KM 0.8 SAN JOSE ITURBIDE, GUANAJUATO. WWW.COLGATE.COM.MX

STEFANO ROYAL

aluminum chlorohydrate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69772-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM CHLOROHYDRATE (UNII: HPN8MZW13M) (ALUMINUM CHLOROHYDRATE - UNII:HPN8MZW13M)	ALUMINUM CHLOROHYDRATE	25 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE SODIUM (UNII: MP1J8420LU)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
WATER (UNII: 059QF0KO0R)	
STEARETH-2 (UNII: V56DFE46J5)	
PPG-15 STEARYL ETHER (UNII: 1II18XLS1L)	
ISO STEARETH-20 (UNII: 78H2SJ8X8M)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69772-050-01	50 mL in 1 APPLICATOR; Type 0: Not a Combination Product	01/29/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part350	01/29/2016	

Labeler - TERESA CECENA DBA GENESIS (078760958)

Registrant - TERESA CECENA (078760958)

Establishment

Name	Address	ID/FEI	Business Operations
TERESA CECENA DBA GENESIS		078760958	relabel(69772-050)

Establishment

Name	Address	ID/FEI	Business Operations
MISSION HILLS		812312122	manufacture(69772-050)

Revised: 1/2016

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