

STEFANO GLADIUS ROLL-ON- 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

Aluminum Chlorohydrate

Purpose:

Antiperspirant

KEEP OUT OF THE REACH OF CHILDREN

USE:

Reduces underarm perspiration

FOR EXTERNAL USE ONLY

DIRECTIONS

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, SOYOIL, STEARTH-2, PPG-15 STEARYL ETHER, STEARETH-20, FRAGRANCE, CAPRYLY GLYCOL. TETRASOSIUM EDTA, AND BHT

DRUG FACTS

Active Ingredient	Purpose
Aluminium Chlorhydrate	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, caprililglycol, 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 GLADIUS ROLL-ON

aluminum chlorohydrate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69772-040
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 100 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: 1H18XLS1L)	

ISOSTEARETH-20 (UNII: 78H2SJ8X8M)

CAPRYLYL GLYCOL (UNII: 00YIU5438U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69772-040-01	50 mL in 1 APPLICATOR; Type 0: Not a Combination Product	06/02/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part350	06/02/2015	

Labeler - Teresa Cecena DBA Genesis (078760958)

Registrant - Teresa (078760958)

Establishment

Name	Address	ID/FEI	Business Operations
Teresa Cecena DBA Genesis		078760958	relabel(69772-040)

Establishment

Name	Address	ID/FEI	Business Operations
Colgate Palmolive S.A. de C.V.		810007526	manufacture(69772-040)

Revised: 6/2015

Teresa Cecena DBA Genesis