

STEFANO FIRE- aluminum chlorohydrate stick
ALL NATURAL DYNAMICS

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.

STEFANO Fire

Active Ingredient:

ALUMINUM CHLOROHYDRATE

Purpose:

Antiperspirant

Keep Out Of The Reach Of Children

USE:

reduces underarm perspiration.

Warnings:

For External Use Only. Do Not Apply On Irritated Or Injured Skin. Discontinue Use If You Experience Some Irritation, Redness Or Discomfort.

Directions:

Apply under arm only.

SHAKE WELL BEFORE USE.

Inactive Ingredients:

Water, Soy oil, steareth-2, PPG-15 stearyl ether, steareth-20, fragrance, caprylyl glycol, tetrasodium EDTA, and BHT



DRUG FACTS


Active Ingredient	Purpose
Aluminum Chlorohydrate 20.0%	Antiperspirant

Use: Reduces underarm perspiration

Warnings:
 For External Use Only.
 Do not use on broken skin.
 Discontinue use if irritation and redness develops. If condition persists for more than 72 hours consult a doctor.
 Keep Out Of Reach Of Children.
 Ask a doctor before use if you have kidney disease.

Directions: Apply underarms only. SHAKE WELL. DRY CHL USE.

Inactive Ingredients: Water, Soy oil, steareth-2, PPG-15 stearyl ether, steareth-20, fragrance, caprilyglycol, tetrasodium EDTA and BHT.



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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 FIRE

aluminum chlorohydrate stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51769-980
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
WATER (UNII: 059QF0KO0R)	
STEARETH-2 (UNII: V56DFE46J5)	
PPG-15 STEARYL ETHER (UNII: 1II18XLS1L)	
STEARETH-20 (UNII: L0Q8IK9E08)	
EDETATE SODIUM (UNII: MP1J8420LU)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
caprylyl glycol (UNII: 00YIU5438U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51769-980-64	50 mL in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part350	05/17/2012	

Labeler - ALL NATURAL DYNAMICS (962732892)

Registrant - ALL NATURAL DYNAMICS (962732892)

Establishment

Name	Address	ID/FEI	Business Operations
Colgate Palmolive, S.A. de C.V.		810007526	manufacture(51769-980)