

COLGATE ZERO CLEAR SPEARMINT- sodium fluoride gel, dentifrice
Mission Hills S.A de C.V

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.

COLGATE® ZERO CLEAR GEL SPEARMINT

Drug Facts

Active ingredient

Sodium Fluoride 0.24% (0.15% w/v fluoride ion)

Purpose

Anticavity

Use

helps protect against cavities

Warnings

Keep out of reach of children under 6 years of age.

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 2 years of age and older	brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician
children 2 to 6 years	use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)
children under 2 years	ask a dentist or physician

Inactive ingredients

Sorbitol, Water, Hydrated Silica, Xylitol, PEG-12, Cellulose Gum, Flavor, Sodium Lauryl Sulfate, Benzyl Alcohol, Rebaudioside A.

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 130 g Tube Carton

NEW

Colgate®
Anticavity Fluoride Toothpaste

zero
0% ARTIFICIAL
FLAVORS • SWEETENERS
PRESERVATIVES • COLORS

CLEAR GEL
SPEARMINT

NET WT
4.6 OZ (130g)

STRENGTHENS ENAMEL AND PROVIDES CLINICALLY PROVEN CAVITY PROTECTION



COLGATE ZERO CLEAR SPEARMINT

sodium fluoride gel, dentifrice

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:65954-789

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	680 mg in 1 g
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
XYLITOL (UNII: VCQ006KQ1E)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
REBAUDIOSIDE A (UNII: B3FUD0528F)	

Product Characteristics

Color	WHITE (Transparent slightly beige)	Score	
Shape		Size	
Flavor	SPEARMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65954-789-46	1 in 1 CARTON	10/02/2019	
1		130 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	10/02/2019	

Labeler - Mission Hills S.A de C.V (812312122)