

HISMILE- sodium fluoride gel
HISMILE PTY LTD

Cotton Candy Flavor Sodium Fluoride Anticavity Toothpaste

Active ingredient

Sodium Fluoride 0.243%
(0.14 w/v fluoride ion)

Purpose

Anticavity

Use

Aids in the prevention of dental cavities.

Warnings

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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.

When using this product

Do not swallow

Do not use in eye area

Directions

Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or use as directed by a dentist or doctor.

Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing).

Supervise children as necessary until capable of using without supervision.

Children under 2 years of age: Consult a dentist or doctor.

Inactive Ingredients

Water
 Sorbitol
 Glycerin
 Hydrated Silica
 Xylitol
 Sodium Phosphate
 Xanthan Gum
 Sodium Lauroyl Sarcosinate
 Tetrapotassium Pyrophosphate
 Methyl Diisopropyl Propionamide
 Sodium Gluconate
 Zinc Lactate
 D&C Red No. 33

Label



Cotton Candy Label.jpg

HISMILE			
sodium fluoride gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83013-323

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.243 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C00X)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
SORBITOL (UNII: 506T60A25R)	
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
XYLITOL (UNII: VCQ006KQ1E)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
ZINC LACTATE (UNII: 2GXR25858Y)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	COTTON CANDY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83013-323-01	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/15/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	07/15/2024	

Labeler - HISMILE PTY LTD (758083252)

Registrant - Accupac LLC (061595175)

Revised: 7/2024

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