HISMILE- candy cane flavor sodium fluoride anticavity toothpaste gel Accupac LLC

Candy Cane 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

When using this product

Do not swallow

Do not use in eye area

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

If more than used for brushing is 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 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.

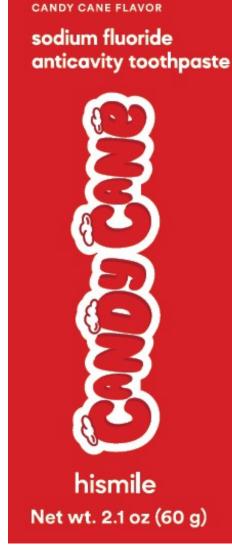
Children under 2 years of age: Consult a dentist or doctor.

Inactive ingredients

Water

Sorbitol Hydrated Silica Glycerin Xylitol Disodium Phosphate Sucralose Sodium Lauroyl Sarcosinate Xanthan Gum Cellulose Gum Flavor Tetrapotassium Pyrophosphate Caprylyl Glycol Benzyl Alcohol Menthol Sodium Gluconate Pentylene Glycol Zinc Lactate Benzoic Acid Methyl Diisopropyl Propionamide Titanium Dioxide

label



Distributed by Hismile Pty Ltd, Burleigh Waters, QLD 4220 AU.

Formulated in Australia. Made in USA.

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PLEASE PEEL AT THE BOTTOM CORNER FOR FULL DRUG FACTS

Drug Facts

Active ingredient

Purpose

Sodium Fluoride 0.24% (0.14% w/v fluoride ion)......Anticavity

Use Aids in the prevention of dental cavities

Warnings

When using this product ■ Do not swallow ■ Do not use in eye area

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 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.

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PLEASE PEEL HERE



HISMILE

candy cane flavor sodium fluoride anticavity toothpaste gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:44038-0327

DENTAL **Route of Administration**

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION -**SODIUM FLUORIDE** 0.243 g in 100 g UNII:Q80VPU408O)

Inactive Ingredients

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	

GLYCERIN (UNII: PDC6A3C0OX)			
PENTYLENE GLYCOL (UNII: 50C1307PZG)			
CAPRYLYL GLYCOL (UNII: 00YIU5438U)			
XANTHAN GUM (UNII: TTV12P4NEE)			
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)			
BENZOIC ACID (UNII: 85KN0B0MIM)			
MENTHOL (UNII: L7T10EIP3A)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
SODIUM GLUCONATE (UNII: R6Q3791S76)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)			
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)			
SORBITOL (UNII: 506T60A25R)			
WATER (UNII: 059QF0KO0R)			
ZINC LACTATE (UNII: 2GXR25858Y)			
BENZYL ALCOHOL (UNII: LKG8494WBH)			
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)			
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)			
f -			

l	P	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1	NDC:44038- 0327-1	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/23/2024			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M021	07/23/2024		
OIC Monograph Drug	MU21	07/23/2024		

Labeler - Accupac LLC (071609663)

Revised: 9/2024 Accupac LLC