

HISMILE- candy cane flavor sodium fluoride anticavity toothpaste gel
HISMILE PTY LTD

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

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.

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

CANDY CANE FLAVOR

**sodium fluoride
anticavity toothpaste**

CANDY CANE

hismile

Net wt. 2.1 oz (60 g)

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

Formulated in Australia.
Made in USA.

www.hismileteeth.com
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PLEASE PEEL AT THE BOTTOM CORNER FOR FULL DRUG FACTS.

Drug Facts

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PLEASE PEEL HERE



Drug Facts (continued)

Inactive ingredients Water, Sorbitol, Hydrated Silica, Glycerin, Xylitol, Disodium Phosphate, Sucralose, Sodium Lauryl 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.

Questions or comments?

+1-302-440-3558

You may also report serious side effects to this phone number.

TRUSTED BY DENTISTS



sugar-free



cruelty-free



no SLS & PEGs



vegan

Hismile uses the highest quality ingredients to provide a superior clean with oral health benefits. Paired with a refreshing burst of flavor, this toothpaste creates a unique smile care experience.

HISMILE

candy cane flavor sodium fluoride anticavity toothpaste gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83013-327
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
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
XYLITOL (UNII: VCQ006KQ1E)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
ZINC LACTATE (UNII: 2GXR25858Y)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
MENTHOL (UNII: L7T10EIP3A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83013-327-06	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/30/2024	

Marketing Information

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

Labeler - HISMILE PTY LTD (758083252)

Establishment

Name	Address	ID/FEI	Business Operations
Accupac LLC		061595175	manufacture(83013-327)