

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

CANDY CANE FLAVOR

sodium fluoride
anticavity toothpaste



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

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
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
HYDRATED SILICA (UNII: Y607T4G8P9)	

GLYCERIN (UNII: PDC6A3C0OX)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
XANTHAN GUM (UNII: TTV12P4NEE)
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)
BENZOIC ACID (UNII: 8SKN0B0MIM)
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: 059QF0K00R)
ZINC LACTATE (UNII: 2GXR25858Y)
BENZYL ALCOHOL (UNII: LKG8494WBH)
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)

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	

Labeler - Accupac LLC (071609663)

Revised: 9/2024

Accupac LLC