

HISMILE- vanilla flavor sodium fluoride anticavity toothpaste gel
Hismile Pty Ltd

Vanilla Flavor Sodium Fluoride Anticavity Toothpaste

Active ingredient

Sodium Fluoride 0.24% (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 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, Xylitol, Glycerin, Disodium Phosphate, Flavor, Sodium Lauroyl Sarcosinate, Xanthan Gum, Cellulose Gum, Tetrapotassium Pyrophosphate, Caprylyl Glycol, Pentylene Glycol, Benzyl Alcohol, Sucralose, Methyl Diisopropyl Propionamide, Sodium Gluconate, Zinc Lactate, Benzoic Acid, Titanium Dioxide

label

Vanilla Flavor Sodium Fluoride Anticavity Toothpaste

Manufactured for:
Hismile Pty Ltd, 225 Burleigh
Connection Rd, Burleigh Waters,
Queensland, Australia 4220.

Formulated in Australia.
Made in USA.

www.hismileteeth.com
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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.

label

VANILLA FLAVOR

**sodium fluoride
anticavity toothpaste**

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Hismile Pty Ltd, 225 Burleigh
Connection Rd, Burleigh Waters,
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PLEASE PEEL AT THE BOTTOM CORNER FOR FULL DRUG FACTS.

smile

Drug Facts	
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Sodium Fluoride 0.24% (0.14% w/v fluoride ion).....	Anticavity
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Warnings When using this product ■ do not swallow ■ do not use in eye area	
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Net wt. 2.1 oz (60 g)

30103124

PLEASE PEEL HERE



Drug Facts (continued)

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

Questions or comments?

+1-302-440-3558

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

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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.

vanilla flavor sodium fluoride anticavity toothpaste gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83013-320
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	2.4 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
XANTHAN GUM (UNII: TTV12P4NEE)	
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
ZINC LACTATE (UNII: 2GXR25858Y)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SORBITOL (UNII: 506T60A25R)	
XYLITOL (UNII: VCQ006KQ1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	VANILLA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83013-320-06	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/15/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	01/15/2024	

Labeler - Hismile Pty Ltd (758083252)

Establishment

Name	Address	ID/FEI	Business Operations
Accupac, LLC		061595175	manufacture(83013-320)

Revised: 1/2024

Hismile Pty Ltd