

**HISMILE VANILLA FLAVOR ANTICAVITY- sodium fluoride paste, dentifrice
HISMILE PTY LTD**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

hismile VANILLA FLAVOR anticavity

Drug Facts

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.

Other information

store in a cool, dry place.

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.

Manufactured for:

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

Formulated in Australia.

Made in Thailand.

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.

Packaging

VANILLA FLAVOR

**sodium fluoride
anticavity toothpaste**

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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

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Net wt. 2.1 oz (60 g)

Use aids in the prevention of dental cavities

Warnings

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■ do not use in eye area

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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. ▶

PLEASE PEEL HERE



Drug Facts (continued)

Other information store in a cool, dry place.

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.

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HISMILE VANILLA FLAVOR ANTICAVITY

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83013-310
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
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
XYLITOL (UNII: VCQ006KQ1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
ZINC LACTATE (UNII: 2GXR25858Y)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	VANILLA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83013-310-06	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/14/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/14/2023	

Labeler - HISMILE PTY LTD (758083252)

Revised: 6/2023

HISMILE PTY LTD