

**HISMILE- smooth mint flavor sodium fluoride anticavity toothpaste gel**  
**Hismile Pty Ltd**

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**Smooth Mint 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, Flavor, Disodium Phosphate, Sodium Lauroyl Sarcosinate, Calcium Glycerophosphate, Xanthan Gum, Cellulose Gum, Tetrapotassium Pyrophosphate, Benzyl Alcohol, Caprylyl Glycol, Sucralose, Menthol, Sodium Gluconate, Pentylene Glycol, Zinc Lactate, Methyl Diisopropyl Propionamide, Benzoic Acid

## **label**

Smooth Mint 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](http://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**

### **Drug Facts** (continued)

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### **Questions or comments?**

+1-302-440-3558

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

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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.

SMOOTH MINT 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  
© Hismile Pty Ltd, 2022



PLEASE PEEL AT THE BOTTOM CORNER FOR FULL DRUG FACTS.

### Drug Facts

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PLEASE PEEL HERE



## HISMILE

smooth mint flavor sodium fluoride anticavity toothpaste gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83013-314
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	<b>SODIUM FLUORIDE</b>	2.4 mg in 1 g
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### Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM GLUCONATE</b> (UNII: R6Q3791S76)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>METHYL DIISOPROPYL PROPIONAMIDE</b> (UNII: 6QOP5A9489)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>POTASSIUM PYROPHOSPHATE</b> (UNII: B9W4019H5G)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>ZINC LACTATE</b> (UNII: 2GXR25858Y)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>WATER</b> (UNII: 059QF0KOOR)	
<b>CALCIUM GLYCEROPHOSPHATE</b> (UNII: XWV9Z12C1C)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Smooth Mint Flavor)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83013-314-06	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/14/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	01/14/2024	

**Labeler** - Hismile Pty Ltd (758083252)

## Establishment

Name	Address	ID/FEI	Business Operations
Accupac, LLC		061595175	manufacture(83013-314)

Revised: 1/2026

Hismile Pty Ltd