

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

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**Strawberry 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**

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**

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, D&C Red No. 33

## **Other information**

Strawberry 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.

STRAWBERRY 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, 2023



PLEASE PEEL AT THE BOTTOM CORNER FOR FULL DRUG FACTS.

### Drug Facts

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PLEASE PEEL HERE



## HISMILE

strawberry flavor sodium fluoride anticavity toothpaste gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83013-318
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	<b>SODIUM FLUORIDE</b>	2.4 mg in 1 g
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### Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>METHYL DIISOPROPYL PROPIONAMIDE</b> (UNII: 6QOP5A9489)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>ZINC LACTATE</b> (UNII: 2GXR25858Y)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>POTASSIUM PYROPHOSPHATE</b> (UNII: B9W4019H5G)	
<b>SODIUM GLUCONATE</b> (UNII: R6Q3791S76)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	STRAWBERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83013-318-06	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(83013-318)

Revised: 1/2026

Hismile Pty Ltd