

**HISMILE GRAPE BUBBLEGUM FLAVOR SODIUM FLUORIDE ANTICAVITY  
TOOTHPAST- sodium fluoride gel**

**Hismile Pty Ltd**

-----  
**Hismile Grape Bubblegum 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

**Keep out of reach of children under 6 years**

Keep out of reach of children under 6 years. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**When using this product**

Do not swallow

Do not use in eye area

**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

Glycerin  
Hydrated Silica  
Xylitol  
Sodium Phosphate  
Xanthan Gum  
Cellulose Gum  
Sodium Lauroyl Sarcosinate  
Tetrapotassium Pyrophosphate  
1,2-Hexanediol  
Sucralose  
Lauryl Glucoside  
Sodium Fluoride  
Methyl Diisopropyl Propionamide  
Sodium Gluconate  
Zinc Lactate  
FD&C Red No.40  
FD&C Blue No.1

**label**

3.8750

GRAPE BUBBLEGUM 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, 2024



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

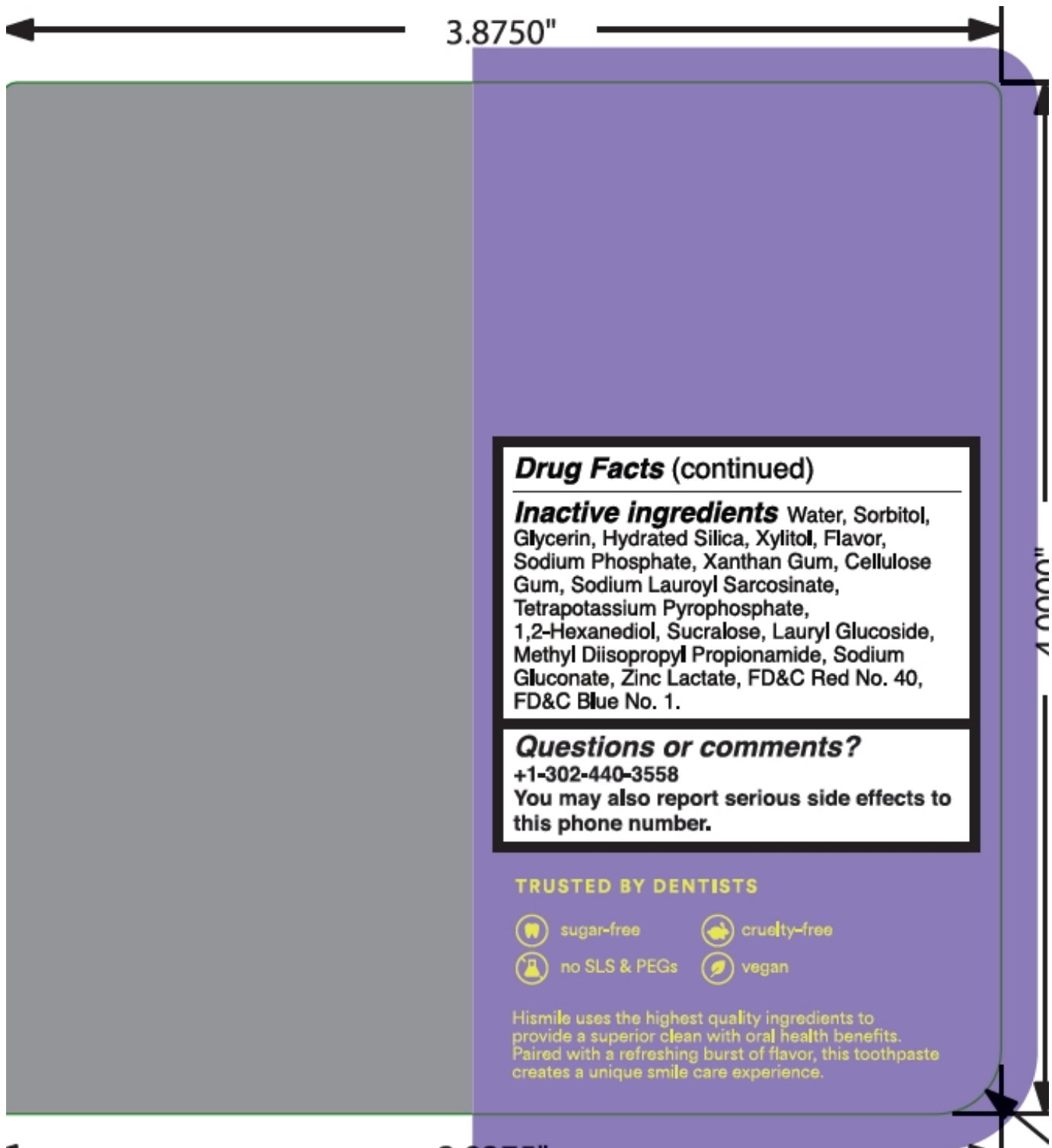
**Directions** ■ Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or use as directed by a dentist or doctor.

- 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.

40007GBLBUS

PLEASE PEEL HERE





## HISMILE GRAPE BUBBLEGUM FLAVOR SODIUM FLUORIDE ANTICAVITY TOOTHPAST

sodium fluoride gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83013-331
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>LAURYL GLUCOSIDE</b> (UNII: 76LN7P7UCU)	
<b>SODIUM GLUCONATE</b> (UNII: R6Q3791S76)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>SODIUM PHOSPHATE</b> (UNII: SE337SVY37)	
<b>CELLULOSE GUM</b> (UNII: K679OBS311)	
<b>TETRAPOTASSIUM PYROPHOSPHATE</b> (UNII: B9W4019H5G)	
<b>METHYL DIISOPROPYL PROPIONAMIDE</b> (UNII: 6QOP5A9489)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>ZINC LACTATE</b> (UNII: 2GXR25858Y)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Product Characteristics**

<b>Color</b>	red (FD&C Red No.40) , blue (FD&C Blue No.1)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE (Apple Grape 1.5 Flavour Flasn 12399)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:83013-331-06	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/09/2025	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M021	01/09/2025	

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

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Accupac LLC		061595175	manufacture(83013-331)

Revised: 3/2025

Hismile Pty Ltd