

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

Grape Bubblegum Flavor Sodium Fluoride Anticavity Toothpaste

Active ingredient

Sodium Fluoride 0.243%
(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

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

Glycerin

Hydrated Silica

Xylitol

Sorbitol

Cellulose Gum

Flavor

1,2-Hexanediol

Sodium Phosphate

Sodium Lauroyl Sarcosinate

Tetrapotassium Pyrophosphate

Sucralose

Caprylyl Glycol

Lauryl Glucoside

Methyl Diisopropyl Propionamide

Sodium Gluconate

Zinc Lactate

Red 40

Blue 1

Label

**GRAPE
BUBBLEGUM
FLAVOR**

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**SODIUM FLUORIDE
ANTICAVITY TOOTHPASTE**

Net wt. 3.5 oz (100g)

Drug Facts

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■ 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
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Inactive ingredients

Water, Glycerin, Hydrated Silica, Xylitol, Sorbitol, Cellulose Gum, Flavor, 1,2-Hexanediol, Sodium Phosphate, Sodium Lauroyl Sarcosinate, Tetrapotassium Pyrophosphate, Sucralose, Caprylyl Glycol, Lauryl Glucoside, Methyl Diisopropyl Propionamide, Sodium Gluconate, Zinc Lactate, Red 40, Blue 1.

Questions or comments?

+1-302-440-3558

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

Distributed by:

Hismile Pty Ltd, Burleigh Waters, QLD 4220 AU.

Formulated in Australia.

Made in USA from globally sourced ingredients and components.

www.hismileteeth.com

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GRAPE BUBBLEGUM FLAVOR SODIUM FLUORIDE ANTICAVITY TOOTHPAST

sodium fluoride gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83013-338	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)		SODIUM FLUORIDE	0.243 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
BLUE 1 (UNII: H3R47K3TBD)				
SODIUM GLUCONATE (UNII: R6Q3791S76)				
WATER (UNII: 059QF0KO0R)				
CAPRYLYL GLYCOL (UNII: 00YIU5438U)				
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)				
HYDRATED SILICA (UNII: Y6O7T4G8P9)				
ZINC LACTATE (UNII: 2GXR25858Y)				
TETRAPOTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)				
RED 40 (UNII: WZB9127XOA)				
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)				
SORBITOL (UNII: 506T60A25R)				
XYLITOL (UNII: VCQ006KQ1E)				
1,2-HEXANEDIOL (UNII: TR046Y3K1G)				
GLYCERIN (UNII: PDC6A3C0OX)				
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83013-338-10	100 g in 1 TUBE; Type 0: Not a Combination Product	10/30/2025	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M021	10/30/2025	

Labeler - HISMILE PTY LTD (758083252)

Establishment			
Name	Address	ID/FEI	Business Operations
Nutrix International, LLC.		117341868	manufacture(83013-338)

Revised: 10/2025

HISMILE PTY LTD