

HISMILE- sodium fluoride gel
HISMILE PTY LTD

Pink Lemonade 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 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

Glycerin

Hydrated Silica

Xylitol

Sodium Phosphate

Xanthan Gum

Sodium Lauroyl Sarcosinate

Tetrapotassium Pyrophosphate

1,2-Hexanediol

Cellulose Gum

Sucralose

Lauryl Glucoside

Methyl Diisopropyl Propionamide

Sodium Gluconate

Zinc Lactate

D&C Red No. 33

label

PINK LEMONADE FLAVOR

sodium fluoride
anticavity toothpaste

his
smile

Net wt. 2.1 oz (60 g)

Distributed by:
HisSmile Pty Ltd, Surleigh
Waters, QLD 4220 AU.

Formulated in Australia.
Made in USA.

www.hismlsreeth.com
© HisSmile 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. ▶

30103988A

PLEASE PEEL HERE



Drug Facts (continued)

Inactive ingredients Water, Sorbitol, Glycerin, Hydrated Silica, Xylitol, Flavor, Sodium Phosphate, Xanthan Gum, Sodium Lauroyl Sarcosinate, Tetrapotassium Pyrophosphate, Sucralose, 1,2-Hexanediol, Cellulose Gum, Lauryl Glucoside, Methyl Diisopropyl Propionamide, Sodium Gluconate, Zinc Lactate, D&C Red No. 33.

Questions or comments?

+1-302-440-3558

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

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.

HISMILE

sodium fluoride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83013-324
Route of Administration	DENTAL		

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
D&C RED NO. 33 (UNII: 9DBA05BB0L)	
XYLITOL (UNII: VCQ006KQ1E)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
GLYCERIN (UNII: PDC6A3C0OX)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
ZINC LACTATE (UNII: 2GXR25858Y)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	LEMON	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83013-324-06	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/15/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	07/15/2024	

Labeler - HISMILE PTY LTD (758083252)

Establishment

Name	Address	ID/FEI	Business Operations
Accupac LLC		061595175	manufacture(83013-324)

