

HISMILE- sodium fluoride gel
Accupac LLC

Blue Raspberry 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-Hexadecanol

Cellulose Gum

Sucralose

Lauryl Glucoside

Methyl Diisopropyl Propionamide

Sodium Gluconate

Zinc Lactate

FD&C Blue No. 1.

Package label

BLUE RASPBERRY 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
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PLEASE PEEL AT THE BOTTOM CORNER FOR FULL DRUG FACTS.

Drug Facts

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■ Children under 2 years of age: Consult a dentist or doctor.

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PLEASE PEEL HERE

HISMILE

sodium fluoride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44038-0326
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.243 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
ZINC LACTATE (UNII: 2GXR25858Y)	

METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)
SORBITOL (UNII: 506T60A25R)
SODIUM GLUCONATE (UNII: R6Q3791S76)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
XANTHAN GUM (UNII: TTV12P4NEE)
GLYCERIN (UNII: PDC6A3C0OX)
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)
HYDRATED SILICA (UNII: Y6O7T4G8P9)
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BLUEBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44038-0326-1	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/23/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	07/23/2024	

Labeler - Accupac LLC (071609663)

Registrant - Accupac LLC (061595175)