

HISMILE- sodium fluoride gel
Accupac LLC

Cherry 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 the 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-Hexnediol
Cellulose Gum
Sucralose
Lauryl Glucoside
Methyl Diisopropyl Propionamide
Sodium Gluconate
Zinc Lactate

label

CHERRY FLAVOR

sodium fluoride
anticavity toothpaste

hismile

Net wt. 2.1 oz (60 g)

Distributed by:
Himile Pty Ltd, Burleigh
Waters, QLD 4220 AU.

Formulated in Australia.
Made in USA.

www.himileteeth.com
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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	
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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.	

30102721A PLEASE PEEL HERE

HISMILE

sodium fluoride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44038-0321
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
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
ZINC LACTATE (UNII: 2GXR25858Y)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
XYLITOL (UNII: VCQ006KQ1E)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44038-0321-1	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/15/2024	

Marketing Information

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

Labeler - Accupac LLC (071609663)

Registrant - Accupac LLC (061595715)

Establishment

Name	Address	ID/FEI	Business Operations
Accupac LLC		061595175	manufacture(44038-0321)

Revised: 9/2024

Accupac LLC