

HISMILE- red velvet flavor sodium fluoride anticavity toothpaste gel
Hismile Pty Ltd

Red Velvet 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

When using this product

- do not swallow
- do not use in eye area

Keep out of reach of children under 6 years of age

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, Hydrated Silica, Xylitol, Glycerin, Flavor, Disodium Phosphate, Sodium Lauroyl Sarcosinate, Xanthan Gum, Cellulose Gum, Tetrapotassium Pyrophosphate, Benzyl Alcohol, Caprylyl Glycol, Sucralose, Menthol, Sodium Gluconate, Pentylene Glycol, Zinc Lactate, Methyl Diisopropyl Propionamide, Benzoic Acid, Calcium Glycerophosphate, D&C Red No.33

Other information

Red Velvet Flavor Sodium Fluoride Anticavity Toothpaste

Manufactured for:

Hismile Pty Ltd, 225 Burleigh
Connection Rd, Burleigh Waters,
Queensland, Australia 4220.

Formulated in Australia.

Made in USA.

www.hismileteeth.com

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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.

label

RED VELVET FLAVOR

sodium fluoride anticavity toothpaste

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PLEASE PEEL AT THE BOTTOM CORNER FOR FULL DRUG FACTS.

hismile

Net wt. 2.1 oz (60 g)

30103120

PLEASE PEEL HERE

Drug Facts

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Drug Facts (continued)

Inactive ingredients Water, Sorbitol, Hydrated Silica, Xylitol, Glycerin, Flavor, Disodium Phosphate, Sodium Lauroyl Sarcosinate, Xanthan Gum, Cellulose Gum, Tetrapotassium Pyrophosphate, Benzyl Alcohol, Pentylene Glycol, Caprylyl Glycol, Sucralose, Methyl Diisopropyl Propionamide, Sodium Gluconate, Zinc Lactate, Benzoic Acid, Calcium Glycero-phosphate, D&C Red No. 33.

Questions or comments?
+1-302-440-3558
You may also report serious side effects to this phone number.

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HISMILE			
red velvet flavor sodium fluoride anticavity toothpaste gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83013-316
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	2.4 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
MENTHOL (UNII: L7T10EIP3A)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CALCIUM GLYCEROPHOSPHATE (UNII: XWV9Z12C1C)	
ZINC LACTATE (UNII: 2GXR25858Y)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
XYLITOL (UNII: VCQ006KQ1E)	
XANTHAN GUM (UNII: TTV12P4NEE)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHOCOLATE (Red Velvet Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83013-316-06	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/14/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	01/14/2024	

Labeler - Hismile Pty Ltd (758083252)

Establishment

Name	Address	ID/FEI	Business Operations
Accupac, LLC		061595175	manufacture(83013-316)

Revised: 1/2024

Hismile Pty Ltd