

**HISMILE RED VELVET FLAVOR ANTICAVITY- sodium fluoride paste, dentifrice  
HISMILE PTY LTD**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

-----

**hismile RED VELVET FLAVOR anticavity**

***Drug Facts***

***Active ingredient***

Sodium Fluoride 0.24%  
(0.14% w/v fluoride ion)

***Purpose***

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.

***Other information***

store in a cool, dry place.

***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 Glycerophosphate, D&C Red No.33.

**Questions or comments?**

**+1-302-440-3558**

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

**Manufactured for:**

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

Formulated in Australia.

**Made in Thailand.**

[www.hismileteeth.com](http://www.hismileteeth.com)

© Hismile Pty Ltd, 2022

**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.

**Packaging**

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 Thailand.**

[www.hismileteeth.com](http://www.hismileteeth.com)  
© Hismile Pty Ltd, 2022

9357 1074

PLEASE PEEL AT THE BOTTOM CORNER FOR FULL DRUG FACTS.

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Sodium Fluoride 0.24% (0.14% w/v fluoride ion)	Anticavity
<b>Use</b> aids in the prevention of dental cavities	

# hisim

## 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. ▶

Net wt. 2.1 oz (60 g)

PLEASE PEEL HERE



## Drug Facts (continued)

**Other information** store in a cool, dry place.

**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 Glycerophosphate, 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 RED VELVET FLAVOR ANTICAVITY

sodium fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83013-306
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>POTASSIUM PYROPHOSPHATE</b> (UNII: B9W4019H5G)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>METHYL DIISOPROPYL PROPIONAMIDE</b> (UNII: 6QOP5A9489)	
<b>SODIUM GLUCONATE</b> (UNII: R6Q3791S76)	
<b>ZINC LACTATE</b> (UNII: 2GXR25858Y)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>CALCIUM GLYCEROPHOSPHATE</b> (UNII: XWW9Z12C1C)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHOCOLATE (RED VELVET)	<b>Imprint Code</b>	

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83013-306-06	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/13/2023	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/13/2023	

**Labeler** - HISMILE PTY LTD (758083252)

Revised: 1/2023

HISMILE PTY LTD