

**HISMILE STRAWBERRY 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 STRAWBERRY 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, Disodium Phosphate, Flavor, Sodium Lauroyl Sarcosinate, Xanthan Gum, Cellulose Gum, Tetrapotassium Pyrophosphate, Caprylyl Glycol, Pentylene Glycol, Benzyl Alcohol, Sucralose, Methyl Diisopropyl Propionamide, Sodium Gluconate, Zinc Lactate, Benzoic Acid, 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

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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.

Packaging

STRAWBERRY 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
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9357 1913

PLEASE PEEL AT THE BOTTOM CORNER FOR FULL DRUG FACTS.

Drug Facts

hisml
rinsin

Active ingredient

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(0.14% w/v fluoride ion)..... Anticavity

Purpose

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

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sodium fluoride paste, dentifrice

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:83013-308 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | SODIUM FLUORIDE | 2.4 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F) | |
| SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311) | |
| POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| PENTYLENE GLYCOL (UNII: 50C1307PZG) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489) | |
| SODIUM GLUCONATE (UNII: R6Q3791S76) | |

| | |
|--|--|
| ZINC LACTATE (UNII: 2GXR25858Y) | |
| BENZOIC ACID (UNII: 8SKN0B0MIM) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |

| Product Characteristics | | | |
|--------------------------------|------------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | STRAWBERRY | Imprint Code | |
| Contains | | | |

| Packaging | | | | |
|------------------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:83013-308-06 | 60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 06/14/2023 | |

| Marketing Information | | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part355 | 06/14/2023 | |

Labeler - HISMILE PTY LTD (758083252)

Revised: 6/2023

HISMILE PTY LTD