

HISMILE- sodium fluoride gel
HISMILE PTY LTD

Wonka 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 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-Hexanediol, Cellulose Gum, Sucralose, Lauryl Glucoside, Methyl Diisopropyl Propionamide, Sodium Gluconate, Zinc Lactate, Iron Oxides

label



HISMILE

sodium fluoride gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:83013-325 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | SODIUM FLUORIDE | 0.243 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618) | |
| 1,2-HEXANEDIOL (UNII: TR046Y3K1G) | |
| FERROUS OXIDE (UNII: G7036X8B5H) | |

| |
|---|
| HYDRATED SILICA (UNII: Y6O7T4G8P9) |
| LAURYL GLUCOSIDE (UNII: 76LN7P7UCU) |
| SUCRALOSE (UNII: 96K6UQ3ZD4) |
| SODIUM GLUCONATE (UNII: R6Q3791S76) |
| METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489) |
| GLYCERIN (UNII: PDC6A3C0OX) |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311) |
| WATER (UNII: 059QF0KO0R) |
| SORBITOL (UNII: 506T60A25R) |
| XYLITOL (UNII: VCQ006KQ1E) |
| SODIUM PHOSPHATE (UNII: SE337SVY37) |
| POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G) |
| ZINC LACTATE (UNII: 2GXR25858Y) |
| XANTHAN GUM (UNII: TTV12P4NEE) |

Product Characteristics

| | | | |
|-----------------|-----------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | CHOCOLATE | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:83013-325-01 | 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 - HISMILE PTY LTD (758083252)

Registrant - Accupac LLC (061595175)