

**SMILESENSE- stannous fluoride paste, dentifrice
SGII, INC**

SmileSense Fluoride Toothpaste

Active ingredient

Stannous Fluoride 0.454% (0.18% W/V Fluoride Ion)

Purpose

Stannous Fluoride 0.454% (0.18% W/V Fluoride Ion).....Anticavity, Antigingivitis, Antisensitivity

Uses

- Aids in the prevention of cavities
- Helps prevent gingivitis
- Helps interfere with the harmful effects of plaque associated with gingivitis
- Builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact

Warnings

When using this product, do not use for sensitivity longer than four weeks unless recommended by a dentist.

Stop use and ask a dentist if

- the sensitivity problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care.
- gingivitis, bleeding, or redness persists for more than 2 weeks.
- you have painful or swollen gums, pus from the gum line, loose teeth, or increased spacing between the teeth.

These may be signs or symptoms of periodontitis, a serious form of gum disease.

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 12 years of age and older: apply at least a 1-inch strip of the product onto a soft bristle toothbrush. In the AM & PM, for up to 2 minutes, gently brush your teeth using small, circular motions or as recommended by a dentist or doctor. Work your way slowly around your mouth, addressing every area of the teeth (outer, inside & chewing surface) including all sensitive areas. Open wide and angle your toothbrush toward the gum line. Rinse your mouth & toothbrush. With fresh

toothpaste, brush the surface of your tongue, with reaching as far as comfortable into your mouth. Rinse again. Follow-up by flossing between all your teeth at least once a day.

- **Do not swallow**
- **children under 12 years: ask a dentist**

Other information

Products containing stannous fluoride may produce surface staining of the teeth. Adequate tooth brushing may prevent these stains, which are not harmful or permanent and may be removed by your dentist.

Inactive ingredients

Caprylic/Capric Triglyceride (Organic Coconut Oil), Isomalt, Hydrated Silica, Xylitol, Sorbitol, Sodium Bicarbonate, Erythritol, Sodium Lauroyl Sarcosinate, Flavor, Xanthan Gum, Menthol, PEG-40 Hydrogenated Castor Oil, Zinc Citrate, Mentha Piperita (Peppermint) Oil, Mentha Viridis (Spearmint) Leaf Oil, Potassium Citrate, Siraitia Grosvenorii (Monkfruit) Fruit Extract, Sodium Saccharin, Potassium Bitartrate, Carbon Dioxide, Sodium Benzoate, Water, Maltodextrin, Carvone, Rebaudioside A, Alcohol Denat., Limonene, Sodium Chloride, Hydrolyzed Gardenia Florida Extract, Glycyrrhizic Acid, Gamma-Terpinene, Titanium Dioxide.

Questions?

+1 949-860-1860

SmileSense

with BritePop Technology

Anticavity, Antigingivitis and Antisensitivity

Fluoride Toothpaste

3.8 oz / 108 g

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Dist. By: SenoGence® Sapulpa, OK 74066
Made in the USA w/ Global Materials

TUBE3427A

Formulated with popping crystals, which provide a unique, fizzy brushing experience. The Organic Coconut Oil included in the formula of SmileSense Toothpaste may not be compatible with all toothbrushes. **Please refer to the QR code on the front of this tube or senogence.com for recommended toothbrushes.**

SMILESENSE

stannous fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72644-639
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.11 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GARDENIA JASMINOIDES WHOLE (UNII: 0PK353KHF0)	
GLYCYRRHIZIN (UNII: 6FO62043WK)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBON DIOXIDE (UNII: 142M471B3J)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CARVONE, (+)- (UNII: 4RWC1CMS3X)	

POTASSIUM CITRATE (UNII: EE90ONI6FF)
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)
ZINC CITRATE (UNII: K72I3DEX9B)
SIRAITIA GROSVENORII FRUIT (UNII: NOU2FB51TW)
SORBITOL (UNII: 506T60A25R)
SODIUM BICARBONATE (UNII: 8MDF5V39QO)
ERYTHRITOL (UNII: RA96B954X6)
MENTHOL (UNII: L7T10EIP3A)
PEPPERMINT OIL (UNII: AV092KU4JH)
SODIUM BENZOATE (UNII: OJ245FE5EU)
WATER (UNII: 059QF0KO0R)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
.GAMMA.-TERPINENE (UNII: 4YGF4PQP49)
ISOMALT (UNII: S870P55O2W)
HYDRATED SILICA (UNII: Y6O7T4G8P9)
XYLITOL (UNII: VCQ006KQ1E)
MALTODEXTRIN (UNII: 7CVR7L4A2D)
REBAUDIOSIDE A (UNII: B3FUD0528F)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)
SPEARMINT OIL (UNII: C3M81465G5)
SACCHARIN SODIUM (UNII: SB8ZUX40TY)
POTASSIUM BITARTRATE (UNII: NPT6P8P3UU)
ALCOHOL (UNII: 3K9958V90M)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72644-639-01	108 g in 1 TUBE; Type 0: Not a Combination Product	07/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	07/01/2024	

Labeler - SGII, INC (070096792)

Establishment

Name	Address	ID/FEI	Business Operations
Dynamic Blending Specialists, Inc.		085704438	manufacture(72644-639)