

**SENSITIVE WHITENING ANTICAVITY- stannous flouride paste, dentifrice
Topco**

5820001 Topco Restore & Defend

Active Ingredient Purpose

Stannous fluoride 0.454% (0.15% w/v fluoride ion) Anticavity/Antihypersensitivity

Uses

- aids in the prevention of dental cavities
- builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact

When using this product, if irritation occurs discontinue use

Stop use and ask a dentist if

- the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist
- pain/sensitivity still persists after 4 weeks of use

Keep out of reach of children. 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

- brush teeth thoroughly for at least one minute twice a day (morning and evening), and not more than 3 times a day, or as recommended by a dentist or doctor. Make sure to brush all sensitive areas of the teeth. Minimize swallowing. Spit out after brushing.
- **children under 12 years of age:** Consult a dentist or doctor.

Other information

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

this product is specifically formulated to prevent staining

store below 30°C (86°F)

glycerin, water, hydrated silica, pentasodium triphosphate, flavor, cocamidopropyl betaine, sodium lauryl sulfate, titanium dioxide, cellulose gum, sodium saccharin

Whitening

Sensitive

Anticavity Toothpaste for Sensitive Teeth

Net Wt 3.4 oz (96.3g)

Compare to Sensodyne

Repair & Protect Active Ingredient*

Restore

& Defend

Builds protective coating on

sensitive areas of teeth

SENSITIVE WHITENING ANTICAVITY

stannous flouride paste, dentifrice

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-201	
Route of Administration	DENTAL			
Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.15 g in 100 g		
Inactive Ingredients				
Ingredient Name	Strength			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
WATER (UNII: 059QF0KO0R)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)				
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
HYDRATED SILICA (UNII: Y607T4G8P9)				
SODIUM TRIPOLYPHOSPHATE ANHYDROUS (UNII: 9SW4PFD2FZ)				
GLYCERIN (UNII: PDC6A3C00X)				
Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-201-19	1 in 1 CARTON	10/31/2019	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M021	10/31/2019		

Labeler - Topco (006935977)

Registrant - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(36800-201) , pack(36800-201)