

**CARE ONE RESTORE AND DEFEND SENSITIVE WHITENING- stannous fluoride paste, dentifrice  
Foodhold U.S.A.**

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**5820293 Care One Restore & Defend Sensitive Whitening Toothpaste**

***Drug Facts***

***Active ingredient***

Stannous Fluoride 0.454% w/w (0.15% fluoride ion)

***Purpose***

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

***Warnings***

**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, preferably after each meal or at least twice a day (morning and evening) or as directed by a dentist or physician. Make sure to brush all sensitive areas of the teeth.
- Do not swallow
- **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 help prevent staining.

- store below 30°C (86°F)

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

***Questions or Comments?* CALL 1-877-846-9949**

DISTRIBUTED BY:

FOODHOLD U.S.A., LLC

LANDOVER, MD 20785

For product questions or concerns, contact us at 1-877-849-9949

CareOne®

**RESTORE & DEFEND SENSITIVE TOOTHPASTE**

FOR SENSITIVE TEETH & CAVITY PROTECTION

DAILY PROTECTION FOR SENSITIVE TEETH

WHITENING

FRESH MINT

NET WT 3.4 OZ (96.3 g)

# CARE ONE RESTORE AND DEFEND SENSITIVE WHITENING

stannous fluoride paste, dentifrice

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-722	
Route of Administration	DENTAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	0.15 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C00X)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
WATER (UNII: 059QF0K00R)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
SODIUM TRIPOLYPHOSPHATE ANHYDROUS (UNII: 9SW4PFD2FZ)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)				
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
HYDRATED SILICA (UNII: Y6O7T4G8P9)				
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:41520-722-19	1 in 1 CARTON	02/11/2019	
1		96.3 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	02/11/2019	

**Labeler -** Foodhold U.S.A. (809183973)

**Registrant -** Lornamead (080046418)

Establishment			
Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(41520-722)