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

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: PDC6A3C0OX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
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 Products (119559733)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		119559733	manufacture(41520-722)

Revised: 11/2025

Foodhold U.S.A.