

**CARE ONE MAXIMUM STRENGTH- fluoride paste, dentifrice**  
**American Sales**

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**5820111 Care One Max Str Sensitive Extra Whitening**

***Active ingredients***

Potassium nitrate 5%

Sodium fluoride 0.24% (0.15% w/v fluoride ion)

***Purpose***

Antihypersensitivity

Anticavity

***Uses***

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

***Warnings***

**When using this product** do not use longer than 4 weeks unless recommended by a dentist or physician.

**See your dentist if** the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.

**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 recommended by a dentist or physician. Make sure to brush all sensitive areas of the teeth.
- **Children under 12 years of age:** consult a dentist or physician.

***Inactive ingredients*** cocamidopropyl betaine, flavor, glycerin, hydrated silica, PEG-8, sodium hydroxide, sodium methyl cocoyl taurate, sodium saccharin, sodium tripolyphosphate, sorbitol, titanium dioxide, water, xanthan gum

***Store in a cool, dry place. Keep tube capped when not in use.***

DISTRIBUTED BY:

American Sales Company

4201 Walden Avenue

Lancaster, NY 14086



## CARE ONE MAXIMUM STRENGTH

fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-582
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.15 g in 100 g
<b>POTASSIUM NITRATE</b> (UNII: RU45X2JNOZ) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM TRIPOLYPHOSPHATE</b> (UNII: 5HK03SA80J)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>SODIUM METHYL COCOYL TAURATE</b> (UNII: JVL98CG53G)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (mint)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-582-19	1 in 1 CARTON	01/20/2013	
1	NDC:41520-582-12	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	M022	01/20/2013	

**Labeler** - American Sales (809183973)

**Registrant** - Lornamead Products (119559733)

### Establishment

Name	Address	ID/FEI	Business Operations
Lornamead Products		119559733	pack(41520-582) , manufacture(41520-582)

Revised: 11/2025

American Sales