
Stannous fluoride 0.454% (0.14% w/v fluoride ion)

Anticavity/Antigingivitis

Keep out of reach of children under 12 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

adults and children 12 years of age and older: brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician * do not swallow * children under 12 years of age: ask a dentist

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 * this product is specifically formulated to help prevent staining * see your dentist regularly

water, hydrated silica, sorbitol, sodium lauryl sulfate, carrageenan, flavor, xanthan gum, zinc citrate, sodium saccharin, sodium hydroxide, sucralose, titanium dioxide

stannous fluoride paste, dentifrice

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11822-5006 |
| Route of Administration | DENTAL | | |

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 0.14 g in 100 g |

| Ingredient Name | Strength |
|--|----------|
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| WATER (UNII: 059QF0K00R) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| CARRAGEENAN (UNII: 5C69YCD2YJ) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| SORBITOL (UNII: 506T60A25R) | |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| ZINC CITRATE (UNII: K72I3DEX9B) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |

| 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:11822-5006-9 | 1 in 1 CARTON | 11/10/2021 | |
| 1 | | 116.2 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 | 11/10/2021 | |

Labeler - Rite Aid (014578892)

Registrant - Lornamead (080046418)

| Establishment | | | |
|---------------|---------|-----------|--|
| Name | Address | ID/FEI | Business Operations |
| Lornamead | | 080046418 | manufacture(11822-5006) , pack(11822-5006) |