

SENSITIVE TOOTH PASTE MULTI ACTION- fluoride gel

CVS Pharmacy

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredients

POTASSIUM NITRATE 5%HYPERSENSITIVITY
SODIUM FLUORIDE (0.15% W/V) FLUORIDE ION.....ANTICAVITY

Use

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

Uses

When using this product if irritation occurs
discontinue use

If pain/sensitivity still persists after 4 weeks
of use, please visit your dentist

Keep out of reach of children

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

Inactive ingredients

Inactive ingredients:

Water, Hydrated Silica, Glycerin, Sorbitol, Potassium Nitrate, PEG-6, Flavor, Isopentane, Xanthan Gum, Chondrus Crispus (Carrageenan), Sodium Methyl Cocoyl Taurate, Cocamidopropyl Betaine, Sodium Saccharin, Sucralose, FD C Blue 1

| Drug Facts | | Drug Facts (continued) |
|---|---|--|
| Active ingredients Potassium Nitrate 5%..... Antihypersensitivity Sodium Fluoride (0.15% w/v fluoride ion).....Articavity | Purpose | 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 doctor. Make sure to brush all sensitive areas of the teeth. • Children under 12 years of age: consult a dentist or doctor. |
| Uses • builds increasing protection against painful sensitivity of the teeth due to cold, heat, acids, sweets or contact • aids in the prevention of dental cavities | Warnings When using this product, if irritation occurs discontinue use. If pain/sensitivity still persists after 4 weeks of use, please visit your dentist. Stop use and see your doctor if the problem 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. Flammable. Contents under pressure. Do not puncture or incinerate container. Do not store at temperatures above 120°F. Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal. | Inactive ingredients Water, Hydrated Silica, Glycerin, Sorbitol, Potassium Nitrate, PEG-6, Flavor, Isopentane, Xanthan Gum, Chondrus Crispus (Carrageenan), Sodium Methyl Cocoyl Taurate, Cocamidopropyl Betaine, Sodium Saccharin, Sucralose, FD&C Blue#1 * This product is not manufactured or distributed by GlaxoSmithKlein, owner of the registered trademark Sensodyne® |

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Best before:
See base of can

Please recycle empty can
Does not contain CFCs

2827195R1 / 5820195

853641
FPO
0 50428 53350 5
0 00000 00000 0

MADE IN CANADA

NET WT. 4.3 OZ (121.6 g)

Warnings

Flammable. Contents under pressure. Do not puncture or incinerate container. Do not store at temperatures above 120 F. Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

SENSITIVE TOOTH PASTE MULTI ACTION

fluoride gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:59 779-8 19

Route of Administration DENTAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| POTASSIUM NITRATE (UNII: RU45X2JN0Z) (POTASSIUM CATION - UNII:295O53K152) | POTASSIUM NITRATE | 5.0 g in 100 g |
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | SODIUM FLUORIDE | 0.15 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|--------------------|
| SORBITOL (UNII: 506T60A25R) | 24.0 g in 100 g |
| WATER (UNII: 059QF0KO0R) | 25.5497 g in 100 g |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | 0.2 g in 100 g |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | 0.01 g in 100 g |
| POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ) | 3.0 g in 100 g |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | 0.00034 g in 100 g |
| GLYCERIN (UNII: PDC6A3C0OX) | 19.0 g in 100 g |
| XANTHAN GUM (UNII: TTV12P4NEE) | 0.7 g in 100 g |
| CHONDRUS CRISPUS (UNII: OQS23HUA1X) | 0.7 g in 100 g |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | 19.0 g in 100 g |
| SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G) | 1.0 g in 100 g |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | 0.4 g in 100 g |
| ISOPENTANE (UNII: ZH67814I0O) | |

Product Characteristics

| | | | |
|----------|-----------------------------------|--------------|--|
| Color | blue (BLUE AND GREEN) | Score | |
| Shape | | Size | |
| Flavor | MINT (Hagelin 622868 Mint Flavor) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:59779-819-58 | 12 in 1 CASE | | |
| 1 | NDC:59779-819-57 | 121.6 g in 1 CAN | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part356 | 12/13/2011 | |

Labeler - CVS Pharmacy (062312574)

Registrant - Lornamead (126440440)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------|---------|-----------|---------------------|
| Lornamead | | 126440440 | manufacture |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|---------------------|
| Assured Packaging Inc | | 248916165 | pack |

Revised: 12/2011

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