

SENSITIVE TOOTH PASTE WHITENING- 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, Sodium Tripolyphosphate, PEG-6, Flavor, Isopentane, Xanthan Gum, Chondrus Crispus (Carrageenan), Sodium Hydroxide, Sodium Methyl Cocoyl Taurate, Cocamidopropyl Betaine, Sodium Saccharin, Sucralose, FD C Blue 1

Web Direction



preferable to keep critical copy at least 0.125" away from diecut

keep critical copy at least 0.0625" away from diecut

ENLARGED TO 150%

Drug Facts	Drug Facts (continued)
<p>Active ingredients</p> <p>Potassium Nitrate 5%.....Antihypersensitivity Sodium Fluoride (0.15% w/v fluoride ion).....Anticavity</p> <p>Use</p> <ul style="list-style-type: none"> builds increasing protection against painful sensitivity of the teeth due to cold, heat, acids, sweets or contact aids in the prevention of dental cavities <p>Warnings</p> <p>When using this product, if irritation occurs discontinue use.</p> <p>If pain/sensitivity still persists after 4 weeks of use, please visit your dentist.</p> <p>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.</p> <p>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.</p> <p>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.</p>	<p>Directions</p> <p>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.</p> <p>Inactive ingredients</p> <p>Water, Hydrated Silica, Glycerin, Sorbitol, Sodium Tripolyphosphate, PEG-6, Flavor, Isopentane, Sodium Methyl Cocoyl Taurate, Xanthan Gum, Chondrus Crispus (Carrageenan), Sodium Hydroxide, Sodium Saccharin, Cocamidopropyl Betaine, Sucralose, FD&C Blue#1</p> <p>* This product is not manufactured or distributed by GlaxoSmithKline, owner of the registered trademark Sensodyne®</p>
<p>Drug Facts</p> <p>Active ingredients</p> <p>Potassium Nitrate 5%.....Antihypersensitivity Sodium Fluoride (0.15% w/v fluoride ion).....Anticavity</p> <p>Use</p> <ul style="list-style-type: none"> builds increasing protection against painful sensitivity of the teeth due to cold, heat, acids, sweets or contact aids in the prevention of dental cavities <p>Warnings</p> <p>When using this product, if irritation occurs discontinue use.</p> <p>If pain/sensitivity still persists after 4 weeks of use, please visit your dentist.</p> <p>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.</p> <p>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.</p> <p>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.</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <p>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.</p> <p>Inactive ingredients</p> <p>Water, Hydrated Silica, Glycerin, Sorbitol, Sodium Tripolyphosphate, PEG-6, Flavor, Isopentane, Sodium Methyl Cocoyl Taurate, Xanthan Gum, Chondrus Crispus (Carrageenan), Sodium Hydroxide, Sodium Saccharin, Cocamidopropyl Betaine, Sucralose, FD&C Blue#1</p> <p>* This product is not manufactured or distributed by GlaxoSmithKline, owner of the registered trademark Sensodyne®</p>

LORNAMEAD, INC.		PROJECT INFO PRODUCTION NOTES	
DATE: JANUARY 24, 2011		<input checked="" type="radio"/> PMS 166	<input checked="" type="radio"/> REFLEX BLUE
PROJECT: CVS ISOACTIVE LABEL, WHITENING		<input type="radio"/> CYAN	<input type="radio"/>
ITEM #: 2821166R3		<input type="radio"/> MAGENTA	<input type="radio"/>
DIELINE #: N/A			
SIZE: 4" x 5.375"			
FILE NAME: CVS_ISOACTIVE_WHITENING_LABEL_2827166R3			
PRINTER: PER ASSURED			
NOTES: R3 - Added "MADE IN CANADA"			
		APPROVALS CREATIVE _____ MARKETING _____ R&D _____ QUALITY _____ PURCHASING _____ CEO _____	

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Warnings

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SENSITIVE TOOTH PASTE WHITENING

fluoride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-816
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)	22.0697 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)	0.0003 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)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.48 g in 100 g
SODIUM TRIPOLYPHOSPHATE (UNII: 5HK03SA80J)	

Product Characteristics

Color	blue (BLUE AND GREEN)	Score	
Shape		Size	
Flavor	MINT (Hagelin 673902 Mint Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-816-68	12 in 1 CASE		
1	NDC:59779-816-67	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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