

HYVEE MAXIMUM STRENGTH- fluoride paste, dentifrice

HyVee Inc

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 / Purpose

Potassium nitrate 5%.....Antihypersensitivity

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

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

Directions

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.

Apply at least a 1-inch strip of the product onto a soft bristle toothbrush. **Children under 12 years of age:** consult a dentist or a doctor.

Other Information

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

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

mm1.jpg

HyVee

maximum strength
Sensitive Toothpaste with Fluoride

For Sensitive Teeth and Cavity Prevention • Relieves Painful Sensitivity

Compare to the active ingredients in Sensodyne**

Extra Whitening

NET WT 4 OZ (113 g)

HyVee

maximum strength
Sensitive Toothpaste with Fluoride

For Sensitive Teeth and Cavity Prevention • Relieves Painful Sensitivity

Compare to the active ingredients in Sensodyne**

Extra Whitening

NET WT 4 OZ (113 g)

Brushing twice a day builds a protective coating against painful sensitivity.

- Contains Potassium Nitrate clinically proven to reduce painful sensitivity.
- Fluoride for cavity protection.
- Great taste keeps mouth feeling fresh & clean.

FOR POSITION ONLY

0 75450 24999 6

DISTRIBUTED BY HY-VEE, INC., WEST DES MOINES, IA 50266
SATISFACTION GUARANTEED, CALL 1-800-289-8343 www.hy-vee.com

2821189R1 / 5820189

MADE IN USA

Drug Facts

Active Ingredients

Potassium nitrate 5%.....Antihypersensitivity Purpose

Sodium fluoride 0.24% (0.16% w/v fluoride ion).....Anticavity Purpose

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.

Drug Facts (continued)

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.

*This product is not manufactured or distributed by GlaxoSmithKline, owners of the registered trademark Sensodyne®.



Compare to the active ingredients in Sensodyne**

maximum strength

Sensitive Toothpaste with Fluoride

For Sensitive Teeth and Cavity Prevention • Relieves Painful Sensitivity

Extra Whitening

NET WT 4 OZ (113 g)

DISTRIBUTED BY HY-VEE, INC., WEST DES MOINES, IA 50266
SATISFACTION GUARANTEED, CALL 1-800-289-8343 www.hy-vee.com

Drug Facts

Active ingredients

Potassium nitrate 5%..... Antipersensitivity
Sodium fluoride 0.24%..... Anticavity
(0.15% w/v fluoride ion)

Purpose

Uses • builds increasing protection against: painful sensitivity of the teeth to cold, heat, acids, sweets or contact
• adds 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.

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

*This product is not manufactured or distributed by GlaxoSmithKline, owners of the trademark Sensodyne®
1821189R1

HYVEE MAXIMUM STRENGTH

fluoride paste, dentifrice

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:42507-189 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | SODIUM FLUORIDE | 0.24 g in 100 g |
| POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844) | NITRATE ION | 5.0 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|-------------------------------------|----------|
| WATER (UNII: 059QF0K00R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |

| | |
|--|--|
| SODIUM TRIPOLYPHOSPHATE (UNII: 5HK03SA80J) | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |
| SORBITOL (UNII: 506T60A25R) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | |
| SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G) | |

Product Characteristics

| | | | |
|-----------------|-------------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | MINT (mint) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:42507-189-99 | 1 in 1 CARTON | | |
| 1 | NDC:42507-189-92 | 113 g in 1 TUBE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part356 | 01/20/2011 | |

Labeler - HyVee Inc (006925671)

Registrant - Lornamead (126440440)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------|---------|-----------|--|
| Lornamead | | 126440440 | manufacture(42507-189) , pack(42507-189) |