

KISS MY FACE ENAMEL EXTRA- potassium nitrate, sodium fluoride gel, dentifrice

Kiss My Face, LLC

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.

Kiss My Face Enamel Extra Cool Mint Gel Toothpaste

Drug Facts

Active ingredient

Potassium Nitrate 5.0% w/w

Sodium Fluoride 0.243% w/w

Purpose

Antihypersensitivity

Anticavity

Uses

- Builds increasing protection against painful due to cold, heat, acids, sweets or contact.
- Aids in the prevention of plaque and tarter build-up.

Warnings

- Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. See your dentist if the problem persists or worsens.
- **Keep out of reach of children under 6 years of age**
- If you accidentally swallow more than used for brushing, contact a Poison Control Center or seek professional assistance immediately.

Directions

- 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 or as recommended by a dentist or doctor.
- Children under 6 years of age: consult a dentist or doctor.

Other information

You may report a serious adverse event from using this product to Kiss My Face LLC, 144 Main St, Gardiner NY 12525.

Inactive ingredients Glycerin, Water, Sorbitol, Hydrated Silica, Xylitol, Calcium Glycerophosphate, Aloe Barbadensis (Aloe Vera) Leaf Extract*, Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Olea Europaea (Olive) Leaf Extract, Stevia Rebaudiana Extract, Natural Flavor, Mentha Piperita (Peppermint) Oil, Menthol, Ammonium Glycyrrhizate (Licorice) Root Extract, Xanthan Gum, Cellulose Gum, Sodium Methyl Cocoyl Taurate, Sodium Lauroyl Saracosinate, Chlorophyllin-Copper Complex, Potassium Sorbate

Dist: Kiss My Face LLC

Gardiner, NY 12525 USA

KISS MY FACE

BREATH BLASTING FRESHNESS

ENAMEL EXTRA

ANTICAVITY FLUORIDE Toothpaste with Xylitol

Cool Mint Gel

HELPS REHARDEN ENAMEL • WHITENS • REDUCES SENSITIVITY

antioxidant defenders™: tea tree oil • olive leaf extract

Net Wt. 4.5 oz (127.6 g)

ENAMEL XTRA

Enamel Xtra Anticavity Fluoride Gel is specially formulated to help:

- re-harden enamel
- prevent cavities
- replenish calcium
- remove plaque
- whiten teeth
- prevent tartar build-up
- reduce sensitivity

Help keep your mouth healthy and feeling fresh with nature's most trusted ingredients:

- Tea Tree Oil
- Xylitol
- Aloe Vera
- Silica
- Olive Leaf Extract
- Peppermint

KISS MY FACE Hey Kissers, Xpect more! Take it to the Xtreme with a formula rich in calcium and minerals to help rebuild enamel and reduce sensitivity. Natural ingredients and Antioxidant Defenders® are Xtra helpful in keeping your mouth healthy, all with the Kiss My Face breath blasting great taste. And there's more! We go the Xtra mile to take good care of the planet, and have always been cruelty-free. One Kiss is all it takes™... for a beautiful smile.

Bob & Steve
Founders & Chief Brushers

BREATH BLASTING FRESHNESS™

ENAMEL XTRA

- HELPS RE-HARDEN ENAMEL
- WHITENS
- REDUCES SENSITIVITY

antioxidant defenders™:

- tea tree oil
- olive leaf extract

Cool Mint Gel

ANTICAVITY FLUORIDE Toothpaste with Xylitol

New!

Net Wt. 4.5 oz
Poids Net 127.6 g

KISS MY FACE

BREATH BLASTING FRESHNESS™

ENAMEL XTRA

HELPS RE-HARDEN ENAMEL • WHITENS • REDUCES SENSITIVITY

antioxidant defenders™ : tea tree oil • olive leaf extract

ANTICAVITY FLUORIDE Toothpaste with Xylitol **Net Wt. 4.5 oz (127.6 g)**

NO Sulfur or Irritants
Artificial Flavors, Colors, Preservatives

CRUELTY-FREE Not tested on animals
No animal ingredients

MADE IN AMERICA Package made in North America

25% more consumer eco-friendly tube

Drug Facts

Active Ingredients:
Potassium Nitrate 1.0% w/w
Sodium Fluoride 0.243% w/w

Purpose:
Anticavity
Whitening

Other Ingredients: You may report a serious adverse event from using this product to Kiss My Face LLC, 344 Main St, Gardner MA 01923

Other Ingredients: Stearic Acid, Sorbitol, Hydroxyethyl Cellulose, Poloxamer 188, Calcium Chloride, Xylitol, Aloe Vera, Xanthan Gum, Sodium Bicarbonate, Hydroxypropyl Methylcellulose, Sodium Chloride, Sweetener, Menthol, Menthyl Salicylate, (S)-(+)-Limonene, (S)-(+)-Limonene Oxide, Olive Leaf Extract, Silica, Hydroxyethyl Cellulose, Xylitol, Tea Tree Oil, Peppermint Oil, Menthyl Salicylate, Potassium Nitrate, Potassium Fluoride, Calcium Hydroxide, Xanthan Gum, Cellulose Gum, Sodium Hydroxide, Calcium Hydroxide, Sodium Lauryl Sulfate, Citrus Essential Oil, Peppermint Oil, Peppermint

Warnings: • Avoid use if you have a known hypersensitivity to any of the ingredients listed above. • Do not use if you are pregnant or nursing. • Do not use if you are allergic to any of the ingredients listed above. • Do not use if you are allergic to any of the ingredients listed above. • Do not use if you are allergic to any of the ingredients listed above.

Directions: Apply at least a 1 inch strip of the product onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute twice a day or as recommended by a dentist or doctor. Children under 6 years of age should be supervised by a parent or caregiver.

Net Wt. Kiss My Face LLC Gardner, MA 01925 USA

KISS MY FACE ENAMEL EXTRA

potassium nitrate, sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65364-403
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 g
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.243 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CALCIUM GLYCEROPHOSPHATE (UNII: XWV9Z12C1C)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SARCOSINATE (UNII: 5PGH842FAU)	
SORBITOL (UNII: 506T60A25R)	
AESCLUS HIPPOCASTANUM SEED OIL (UNII: E0M52HIR1Y)	
TEA TREE OIL (UNII: VIF565UC2G)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MENTHOL (UNII: L7T10EIP3A)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM COPPER CHLOROPHYLLIN (UNII: 1D276TYV9O)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
MENTHA PIPERITA (UNII: 79M2M2UDA9)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65364-403-27	1 in 1 CARTON	04/01/2015	
1		127.6 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 not final	part356	04/01/2015	

Labeler - Kiss My Face, LLC (041794279)

Registrant - Lornamead Inc. (078584069)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead Inc.		078584069	manufacture(65364-403)

