

SENSODYNE PRONAMEL MINERAL BOOST REFRESHING PEPPERMINT- potassium nitrate and sodium fluoride paste

SENSODYNE PRONAMEL MINERAL BOOST WHITENING ACTION- potassium nitrate and sodium fluoride paste

GlaxoSmithKline Consumer Healthcare Holdings (US) 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.

Drug Facts

Active ingredient

Potassium nitrate 5%

Sodium fluoride 0.25% (0.15% w/v fluoride ion)

Purpose

Antihypersensitivity

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.

Warnings

Stop use and ask a dentist if

- the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.
- pain/sensitivity still persists after 4 weeks of use.

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 1 minute twice a day (morning and evening), and not more than 3 times a day, or as recommended by a dentist or doctor. Make sure to brush all sensitive areas of the teeth. Minimize swallowing. Spit out after brushing

- **children under 12 years of age:** Consult a dentist or doctor.

Other information

- do not store above 25°C (77°F)

Inactive ingredients (refreshing peppermint)

water, sorbitol, hydrated silica, glycerin, flavor, cocamidopropyl betaine, xanthan gum, titanium dioxide, sodium saccharin

Inactive ingredients (whitening action)

water, sorbitol, hydrated silica, glycerin, cocamidopropyl betaine, flavor, xanthan gum, titanium dioxide, sodium saccharin, sodium hydroxide

Questions or comments?

1-866-844-2797

Additional Information

Does not contain: SLS/sulfates • artificial dyes • parabens • triclosan • peroxide

Minerals keep enamel strong and white. But acidic foods & drinks can dissolve surface minerals. Your saliva naturally replenishes minerals but can't always keep up, leading to enamel loss.

Pronamel Mineral Boost improves natural mineral absorption for strong white teeth, protected from sensitivity.

ACIDS DISSOLVE SURFACE MINERALS...

...PRONAMEL BOOSTS MINERAL ABSORPTION FROM SALIVA

Replenishes vital minerals in enamel.

Developed to maximize the effect of fluoride to boost the absorption of calcium & phosphate into the enamel surface.

With twice-daily brushing, Pronamel helps to:

- Protect against effects of dietary acids
- Prevent enamel loss
- Relieve sensitive teeth
- Protect against cavities
- Clean and freshen your mouth

Recyclable Carton

Save Water

Turn off tap while brushing

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Distributed by:

GSK Consumer Healthcare

Warren, NJ 07059

Principal Display Panel

NDC 0135-0450-01

SENSODYNE

PRONAMEL

MINERAL BOOST

new

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

Replenishes Vital Minerals

For Stronger, Healthier Enamel

infused with refreshing peppermint

NET WT 4.0 OZ (113g)

gsk

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NDC 0135-0450-01



Principal Display Panel

NDC 0135-0480-01

SENSODYNE

PRONAMEL

MINERAL BOOST

new

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

Replenishes Vital Minerals

For Stronger, Healthier Enamel

With gentle whitening action

NET WT 4.0 OZ (113g)

gsk

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NDC 0135-0480-01



SENSODYNE PRONAMEL MINERAL BOOST REFRESHING PEPPERMINT

potassium nitrate and sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0450
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	50 mg in 1 g
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.15 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

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:0135-0450-01	1 in 1 CARTON	01/04/2021	
1		118 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	01/04/2021	

SENSODYNE PRONAMEL MINERAL BOOST WHITENING ACTION

potassium nitrate and sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0480
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	50 mg in 1 g
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XANTHAN GUM (UNII: TTV12P4NEE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

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:0135-0480-01	1 in 1 CARTON	01/04/2021	
1		118 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0480-02	1 in 1 CARTON	01/04/2021	
2		77 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	01/04/2021	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 8/2020

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC