

SENSODYNE PRONAMEL INTENSIVE ENAMEL REPAIR CLEAN MINT- potassium nitrate and sodium fluoride paste
SENSODYNE PRONAMEL INTENSIVE ENAMEL REPAIR EXTRA FRESH- potassium nitrate and sodium fluoride paste
SENSODYNE PRONAMEL INTENSIVE ENAMEL REPAIR WHITENING- potassium nitrate and sodium fluoride paste
GlaxoSmithKline Consumer Healthcare Holdings (US)

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

When using this product,

if irritation occurs discontinue use.

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 (Clean Mint, Extra Fresh)

store below 25°C (77°F)

Inactive ingredients (Clean Mint)

water, sorbitol, hydrated silica, glycerin, PEG-8, sodium lactate, flavor, cocamidopropyl betaine, titanium dioxide, xanthan gum, sodium saccharin, PVM/MA copolymer, sodium hydroxide

Inactive ingredients (Extra Fresh)

water, sorbitol, hydrated silica, glycerin, PEG-8, sodium lactate, flavor, cocamidopropyl betaine, titanium dioxide, xanthan gum, sodium saccharin, PVM/MA copolymer, sodium hydroxide

Inactive Ingredients (Whitening)

water, sorbitol, hydrated silica, glycerin, PEG-8, sodium lactate, flavor, cocamidopropyl betaine, titanium dioxide, xanthan gum, sodium saccharin, PVM/MA copolymer, sodium hydroxide

Questions or comments?

Call toll-free **1-866-844-2797**

Principal Display Panel

NDC 0135-0492-01

SENSODYNE

PRONAMEL

INTENSIVE ENAMEL REPAIR

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

CLEAN MINT

ACTIVELY REPAIRS WEAKENED ENAMEL*

NET WT 3.4 OZ (96.4 g)

SENSODYNE

PRONAMEL

INTENSIVE ENAMEL REPAIR

***Sensodyne Pronamel Intensive Enamel Repair** is proven to **drive minerals deep** into the enamel surface to help **actively repair** acid-weakened areas of the enamel, for stronger, better-protected teeth.

PRONAMEL ACTIVELY REPAIRS WEAKENED ENAMEL

LOCKS IN MINERALS

FOR STRONG HEALTHY TEETH

Acids in modern diets can weaken your enamel surface. Over time, this can lead to your enamel thinning, allowing the yellow dull dentin layer underneath to show through. Once your enamel surface is weakened it needs extra care for the future.

With twice-daily brushing, Sensodyne Pronamel Intensive Enamel Repair helps to:

- Actively repair acid-weakened enamel
- Lock in minerals to protect against the effects of acid wear
- Protect against cavities

Sensodyne Pronamel Intensive Enamel Repair is suitable for sensitive teeth.

ALWAYS FOLLOW THE LABEL

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Warren, NJ 07059

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Principal Display Panel

NDC 0135-0486-01

SENSODYNE

PRONAMEL

INTENSIVE ENAMEL REPAIR

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

EXTRA FRESH

ACTIVELY REPAIRS WEAKENED ENAMEL*

NET WT 3.4 OZ (96.4 g)

SENSODYNE

PRONAMEL

INTENSIVE ENAMEL REPAIR

***Sensodyne Pronamel Intensive Enamel Repair** is proven to **drive minerals deep** into the enamel surface to help **actively repair** acid-weakened areas of the enamel, for stronger, better-protected teeth.

PRONAMEL ACTIVELY REPAIRS WEAKENED ENAMEL

LOCKS IN MINERALS

FOR STRONG HEALTHY TEETH

Acids in modern diets can weaken your enamel surface. Over time, this can lead to your enamel thinning, allowing the yellow dull dentin layer underneath to show through. Once your enamel surface is weakened it needs extra care for the future.

With twice-daily brushing, Sensodyne Pronamel Intensive Enamel Repair helps to:

- Actively repair acid-weakened enamel
- Lock in minerals to protect against the effects of acid wear
- Protect against cavities

Sensodyne Pronamel Intensive Enamel Repair is suitable for sensitive teeth.

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Principal Display Panel

NDC 0135-0481-01

New

SENSODYNE

PRONAMEL

INTENSIVE ENAMEL REPAIR

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

WHITENING

ACTIVELY REPAIRS WEAKENED ENAMEL*

NET WT 3.4 OZ (96.4 g)

SENSODYNE

PRONAMEL

INTENSIVE ENAMEL REPAIR

WHITENING

***Sensodyne Pronamel Intensive Enamel Repair** is proven to **drive minerals deep** into the enamel surface to help **actively repair** acid-weakened areas of the enamel, for stronger, better-protected teeth.

PRONAMEL ACTIVELY REPAIRS WEAKENED ENAMEL

LOCKS IN MINERALS

FOR STRONG HEALTHY TEETH

Actively repairs enamel weakened by dietary acids and helps whiten teeth

With twice-daily brushing, Sensodyne Pronamel Intensive Enamel Repair Whitening helps to:

- Lock in minerals to protect against the effects of acid wear
- Protect against cavities
- Effectively removes stains to whiten teeth
- Restore natural whiteness of teeth

Sensodyne Pronamel Intensive Enamel Repair is suitable for sensitive teeth.

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SENSODYNE PRONAMEL INTENSIVE ENAMEL REPAIR CLEAN MINT

potassium nitrate and sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0492
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: Y607T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	MINT (Clean Mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0492-01	1 in 1 CARTON	11/29/2018	
1		96.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0492-02	1 in 1 CARTON	11/29/2018	
2		23 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0135-0492-03	23 g in 1 TUBE; Type 0: Not a Combination Product	01/02/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	11/29/2018	

SENSODYNE PRONAMEL INTENSIVE ENAMEL REPAIR EXTRA FRESH

potassium nitrate and sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0486
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)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	MINT (Extra Fresh)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0486-01	1 in 1 CARTON	11/29/2018	
1		96.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0486-02	2 in 1 CARTON	01/06/2020	
2		96.4 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
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SENSODYNE PRONAMEL INTENSIVE ENAMEL REPAIR WHITENING

potassium nitrate and sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0481
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:Q80VPU4080)	FLUORIDE ION	1.15 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	MINT (Arctic Breeze)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0481-01	1 in 1 CARTON	01/06/2020	
1		96.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0481-02	2 in 1 CARTON	01/06/2020	

2	96.4 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	01/06/2020	

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

Establishment

Name	Address	ID/FEI	Business Operations
BERNARDY		263254254	API MANUFACTURE(0135-0492, 0135-0486, 0135-0481)

Revised: 9/2022

GlaxoSmithKline Consumer Healthcare Holdings (US)