

SENSODYNE PRONAMEL GENTLE WHITENING- potassium nitrate and sodium fluoride paste

SENSODYNE PRONAMEL DAILY PROTECTION- potassium nitrate and sodium fluoride paste

SENSODYNE PRONAMEL FRESH BREATH- potassium nitrate and sodium fluoride paste

SENSODYNE PRONAMEL MULTI 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 ingredients

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 (Gentle Whitening, Daily Protection, Fresh Breath, Multi-Action)

store below 30°C (86°F)

Inactive ingredients (Gentle Whitening)

water, sorbitol, hydrated silica, glycerin, PEG-8, cocamidopropyl betaine, flavor, titanium dioxide, xanthan gum, sodium saccharin, sodium hydroxide

Inactive ingredients (Daily Protection)

water, sorbitol, hydrated silica, glycerin, PEG-8, cocamidopropyl betaine, flavor, xanthan gum, sodium saccharin, titanium dioxide, sodium hydroxide

Inactive ingredients (Fresh Breath)

water, sorbitol, hydrated silica, glycerin, PEG-8, cocamidopropyl betaine, flavor, xanthan gum, sodium saccharin, titanium dioxide, sodium hydroxide

Inactive ingredients (Multi-Action)

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

Questions or comments?

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

Principal Display Panel

NDC 0135-0484-01

SENSODYNE

PRONAMEL

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

GENTLE WHITENING

STRENGTHENS AND RE-HARDENS ENAMEL

PROTECTS AGAINST THE EFFECTS OF ACID EROSION*

NET WT 4.0 OZ (113g)

WINE ACIDS

FRUIT ACIDS

SODA ACIDS

9 OUT OF 10 DENTISTS' RECOMMENDED BRAND

#1 Dentist Recommended Brand for Strengthening & Protecting Enamel†

MULTI-ACTION

ACID PROTECTION FORMULA

SENSODYNE PRONAMEL GENTLE WHITENING

Brushing twice a day with ProNamel helps to:

- Protect enamel against the effects of acid erosion
- Restore natural whiteness
- Clean effectively and freshen breath
- Provide cavity protection
- Maintain healthy teeth and gums

Pronamel is also suitable for people with sensitive teeth.

Help protect your enamel against the effects acid erosion.

Dentists have reported a growing dental health concern due to changing modern diets: **'acid erosion'**. Even teeth without cavities can be affected.

*Acids in everyday food such as some fruit and acidic drinks, like orange juice and wine, can dissolve minerals from our teeth, softening the enamel surface which is then more easily worn away. As the enamel becomes thinner, teeth can become visibly less white, weaker, and sensitive.

SENSODYNE PRONAMEL Gentle Whitening toothpaste is formulated to protect against the effects of acid erosion and also gently, yet effectively remove stains, helping restore teeth to their natural whiteness. As it contains fluoride it also provides all the benefits of a regular toothpaste.

#1 Dentist Recommended Brand For Strengthening and Protecting Enamel.

†Dentists have been recommending Sensodyne for the past 20 years. ProNamel is from the makers of Sensodyne and is highly recommended by dentists. Brushing twice a day with ProNamel toothpaste strengthens enamel and protects against future acid attacks.

And, since ProNamel has fluoride it helps protect against cavities too.

ALWAYS FOLLOW THE LABEL

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GSK Consumer Healthcare

Warren, NJ 07059

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Principal Display Panel

NDC 0135-0460-01

SENSODYNE

PRONAMEL

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

DAILY PROTECTION

STRENGTHENS AND RE-HARDENS ENAMEL

PROTECTS AGAINST THE EFFECTS OF ACID EROSION*

MINTESSENCE

ALPINE BREEZE

NET WT 4.0 OZ (113g)

WINE ACIDS

FRUIT ACIDS

SODA ACIDS

9 OUT OF 10 DENTISTS' RECOMMENDED BRAND

#1 Dentist Recommended Brand for Strengthening and Protecting Enamel†

SENSODYNE PRONAMEL DAILY PROTECTION

USE WHENEVER YOU NORMALLY BRUSH

- Freshens breath
- Helps protect teeth against the effects of Acid Erosion
- Strengthens and re-hardens enamel
- Contains fluoride for cavity protection
- Suitable for sensitive teeth

ProNamel is also suitable for people with sensitive teeth.

Help protect your enamel against the effects of acid erosion.

*Acids in everyday food such as some fruit and acidic drinks, like orange juice and wine, can dissolve minerals from our teeth, softening the enamel surface which is then more easily worn away. As the enamel becomes thinner, teeth can become visibly less white, weaker and sensitive.

SENSODYNE PRONAMEL DAILY PROTECTION toothpaste is formulated to help protect against the effects of acid erosion and also gently, yet effectively remove stains, helping restore teeth to their natural whiteness. As it contains fluoride it also provides all the benefits of a regular toothpaste.

#1 Dentist Recommended Brand For Strengthening and Protecting Enamel.

† Dentists have been recommending Sensodyne for the past 20 years. ProNamel is from the makers of Sensodyne and is highly recommended by dentists. Brushing twice a day with ProNamel toothpaste strengthens enamel and protects against future acid attacks. And, since ProNamel toothpaste has fluoride it helps protect against cavities too.

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This product contains no sugar.

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NDC 0135-0520-01

SENSODYNE

PRONAMEL

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

FRESH BREATH

STRENGTHENS AND RE-HARDENS ENAMEL

PROTECTS AGAINST THE EFFECTS OF ACID EROSION*

FRESH WAVE

NET WT 4.0 OZ (113 g)

WINE ACIDS

FRUIT ACIDS

SODA ACIDS

9 OUT OF 10 DENTISTS' RECOMMENDED BRAND

#1 Dentist Recommended Brand for Strengthening and Protecting Enamel†

MULTI-ACTION

ACID PROTECTON FORMULA

SENSODYNE PRONAMEL FRESH BREATH

Brushing twice a day with ProNamel helps to:

- Protect enamel against the effects of acid erosion
- Freshen breath

- Strengthen and re-harden enamel
- Protect against cavities
- ProNamel is also suitable for people with sensitive teeth

Help protect your enamel against the effects of acid erosion.

*Acids in everyday food such as some fruit and acidic drinks, like orange juice and wine, can dissolve minerals from our teeth, softening the enamel surface which is then more easily worn away. As the enamel becomes thinner, teeth can become visibly less white, weaker and sensitive.

SENSODYNE PRONAMEL Fresh Breath toothpaste is formulated to help protect against the effects of acid erosion. It also contains fluoride providing the benefits of a regular toothpaste

#1 Dentist Recommended Brand For Strengthening and Protecting Enamel.

†Dentists have been recommending Sensodyne for the past 20 years. ProNamel is from the makers of Sensodyne and is highly recommended by dentists. Brushing twice a day with ProNamel toothpaste strengthens enamel and protects against future acid attacks. And, since ProNamel toothpaste has fluoride it helps protect against cavities too.

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Principal Display Panel

NDC 0135-0568-04

SENSODYNE

PRONAMEL

TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

MULTI-ACTION

STRENGTHENS AND RE-HARDENS ENAMEL

PROTECTS AGAINST THE EFFECTS OF ACID EROSION*

Cleansing Mint

WINE ACIDS

FRUIT ACIDS

SODA ACIDS

NET WT 4.0 OZ (113 g)

9 OUT OF 10 DENTISTS' RECOMMENDED BRAND

#1 Dentist Recommended Brand for Strengthening and Protecting Enamel†

MULTI-ACTION

ACID PROTECTION FORMULA

SENSODYNE PRONAMEL MULTI-ACTION

Brushing twice a day with ProNamel helps to:

- Protect enamel against the effects of acid erosion
- Restore natural whiteness
- Clean effectively and freshen breath
- Provide cavity protection
- Maintain healthy teeth

ProNamel is also suitable for people with sensitive teeth.

Help protect your enamel against the effects of acid erosion.

Dentists have reported a growing dental health concern due to changing modern diets: **'acid erosion'**. Even teeth without cavities can be affected.

*Acids in everyday food such as some fruit and acidic drinks, like orange juice and wine, can dissolve minerals from our teeth, softening the enamel surface which is then more easily worn away. As the enamel becomes thinner, teeth can become visibly less white, weaker and sensitive.

SENSODYNE PRONAMEL Multi-Action toothpaste is formulated to help protect against the effects of acid erosion and also gently, yet effectively remove stains, helping restore teeth to their natural whiteness. As it contains fluoride it also provides the benefits of a regular toothpaste. Plus, its cleansing mint flavor helps keep your mouth feeling fresh

and clean.

#1 Dentist Recommended Brand For Strengthening and Protecting Enamel.

†Dentists have been recommending Sensodyne for the past 20 years. ProNamel is from the makers of Sensodyne and is highly recommended by dentists. Brushing twice a day with ProNamel toothpaste strengthens enamel and protects against future acid attacks. And, since ProNamel toothpaste has fluoride it helps protect against cavities too.

ALWAYS FOLLOW THE LABEL

This product contains no sugar.

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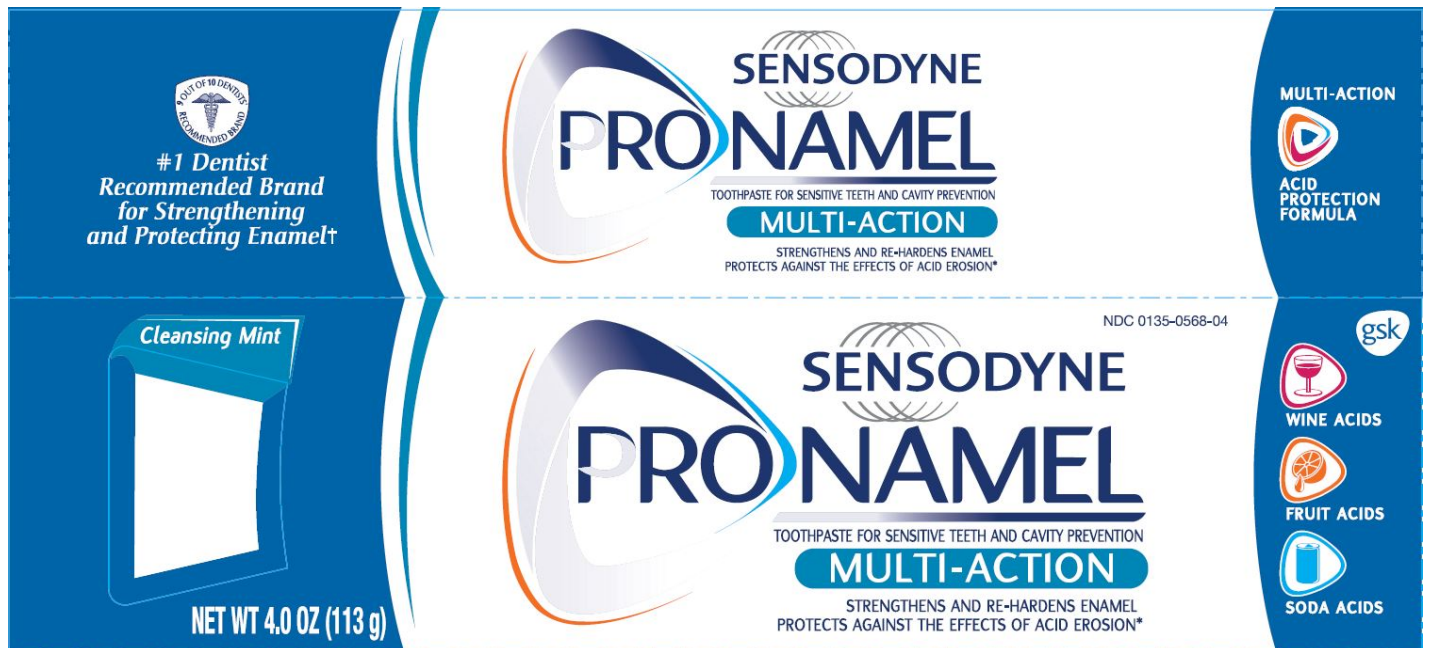
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1-866-844-2797

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SENSODYNE PRONAMEL GENTLE WHITENING

potassium nitrate and sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0484
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: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
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 (alpine breeze)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0484-01	1 in 1 CARTON	10/18/2010	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0484-05	2 in 1 CARTON	10/18/2010	
2		113 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0135-0484-02	1 in 1 CARTON	10/18/2010	
3		76.5 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:0135-0484-03	22.6 g in 1 TUBE; Type 0: Not a Combination Product	10/18/2010	
5	NDC:0135-0484-04	1 in 1 CARTON	07/01/2019	
5		184.3 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:0135-0484-06	4 in 1 CARTON	12/16/2014	
6		184.3 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	10/18/2010	

SENSODYNE PRONAMEL DAILY PROTECTION

potassium nitrate and sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0460
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)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0460-01	1 in 1 CARTON	10/18/2010	

1		113 g in 1 TUBE; Type 0: Not a Combination Product	
2	NDC:0135-0460-06	2 in 1 CARTON	11/29/2017
2		113 g in 1 TUBE; Type 0: Not a Combination Product	
3	NDC:0135-0460-03	1 in 1 CARTON	10/18/2010
3		184.3 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	10/18/2010	

SENSODYNE PRONAMEL FRESH BREATH

potassium nitrate and sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0520
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)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	WHITE	Score	
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Shape		Size	
Flavor	MINT (fresh wave)	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0520-01	1 in 1 CARTON	04/14/2011	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0520-02	23 g in 1 TUBE; Type 0: Not a Combination Product	04/14/2011	
3	NDC:0135-0520-05	2 in 1 CARTON	04/14/2011	
3		113 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:0135-0520-06	1 in 1 CARTON	03/20/2015	
4		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	04/14/2011	

SENSODYNE PRONAMEL MULTI ACTION

potassium nitrate and sodium fluoride paste

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0568
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: Y6O7T4G8P9)	

GLYCERIN (UNII: PDC6A3C0OX)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0568-04	1 in 1 CARTON	12/09/2013	
1		113 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	12/09/2013	

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

Revised: 7/2022

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC