

**PRONAMEL REPAIR WHITENING- pronamel repair whitening paste, dentifrice  
Publix Super Market Inc**

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**5820074 Publix Enamel Guard Intensive (8015074)**

potassium nitrate 5%

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

Antihypersensitivity

Anticavity

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, of irritation occurs discontinue use.

Stop use and ask a dentist if the problem persists or worsen. Sensitive teeth may indicate a serious problem that many 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.

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 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.

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

# Enamel Guard Intensive

TOOTHPASTE FOR SENSITIVE TEETH & CAVITY PREVENTION

- Helps repair tooth enamel with acid protection formula<sup>1</sup>
- For stronger, healthier teeth

Compare to the active ingredients in Sensodyne® Pronamel® intense enamel repair\*



WHITENING

NET WT 3.4 OZ (96.3 g)

100%

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WHITENING

NET WT 3.4 OZ (96.3 g)

Twice daily brushing with Enamel Guard Intensive helps to:

- Repair acid-weakened enamel.
- Protect against the effects of acid erosion.
- Provide sensitivity relief and lasting sensitivity protection.
- Whiten teeth & freshen breath.
- Keep teeth healthy.

\*Guards teeth against sensitivity and the effects of acid wear through normal brushing.



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5820074

### Drug Facts

**Active ingredients** Potassium nitrate 5%..... Antihypersensitivity Purpose  
Sodium fluoride 0,25% (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

**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.

### 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 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.

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

\*This product is not manufactured or distributed by Haleon US Holdings LLC, owner of the registered trademark Sensodyne®.

071103



## PRONAMEL REPAIR WHITENING

pronamel repair whitening paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:56062-514
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>POTASSIUM NITRATE</b> (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 g
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.15 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-514-44	1 in 1 CARTON	09/01/2024	
1		96.3 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 Drug	M022	09/01/2024	

**Labeler** - Publix Super Market Inc (006922009)

**Registrant** - Lornamead (080046418)

### Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	pack(56062-514) , manufacture(56062-514)

Revised: 1/2025

Publix Super Market Inc