

**PRONAMEL REPAIR WHITENING- fluoride paste, dentifrice**  
**Rite Aid**

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**5820076 Rite Aid Enamel Guard Intensive (8015074)**

Potassium nitrate 5% ..... Antihypersensitivity

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

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 stil persists after 4 weeks of use.

Anthihypersensitivity

Anticavity

builds increasing protection against painful sensitivy of the teeth to cold, acids, sweets, or contact. Aids in the prevention of dental cavities.

If more than used for brushing is accidentally swallowed, get medical help or contact a Posion Control Center right away.

**adults and children 12 years of age and older:** apply at least a 1-inch strip of the product ontp 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



## PRONAMEL REPAIR WHITENING

fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-6310
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.15 g in 100 g
<b>POTASSIUM NITRATE</b> (UNII: RU45X2JNOZ) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	

### Product Characteristics

<b>Color</b>	white (White)	<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:11822-6310-1	1 in 1 CARTON	12/01/2024	
1		96 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	12/01/2024	

**Labeler** - Rite Aid (014578892)

**Registrant** - Lornamead (080046418)

### Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(11822-6310) , pack(11822-6310)