

RITE AID ENAMEL GUARD- fluoride paste, dentifrice

Rite Aid

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.

Rite Aid Enamel Guard

Drug Facts

Active ingredients

Potassium nitrate 5%

Sodium fluoride 0.15% w/v fluoride ion

Purpose

Antihypersensitivity

Anticavity

Uses

- aids in the prevention of dental caviites
- aids in reducing sensitivity

Warnings

If pain/sensitivity persists after 4 weeks of use, please visit your dentist.

Stop use and see your doctor if the problem worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.

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 one minute, preferably after each meal or at least twice a day (morning and evening) or as directed by a dentist or physician. Make sure to brush all sensitive areas of the teeth.
- **Children under 12 years of age:** consult a dentist or doctor.

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

Store in a cool, dry place.

DISTRIBUTED BY:

RITE AID, 30 HUNTER LANE

CAMP HILL, PA 17011

MADE IN USA

RITE AID® PHARMACY

oral care

enamel guard

gentle whitening for sensitive teeth

alpine mint

NET WT 4 OZ (113 g)



RITE AID ENAMEL GUARD

fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-6020
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.15 g in 100 g
POTASSIUM NITRITE (UNII: 794654G42L) (NITRITE ION - UNII:J39976L608)	POTASSIUM NITRITE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
XANTHAN GUM (UNII: TTV12P4NEE)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:11822-6020-9	1 in 1 CARTON	06/03/2013	
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	06/03/2013	

Labeler - Rite Aid (014578892)**Registrant** - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(11822-6020)

Revised: 1/2023

Rite Aid