

**NATURAL ADULT FLUORIDE- sodium monofluorophosphate paste  
Kroger**

*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.*

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**5820023 Natural Adult Fluoride**

Active ingredient Purpose

Sodium monofluorophosphate 0.76% (0.13% w/v fluoride ion) . . . Anticavity

**Uses**

aids in the prevention of dental cavities

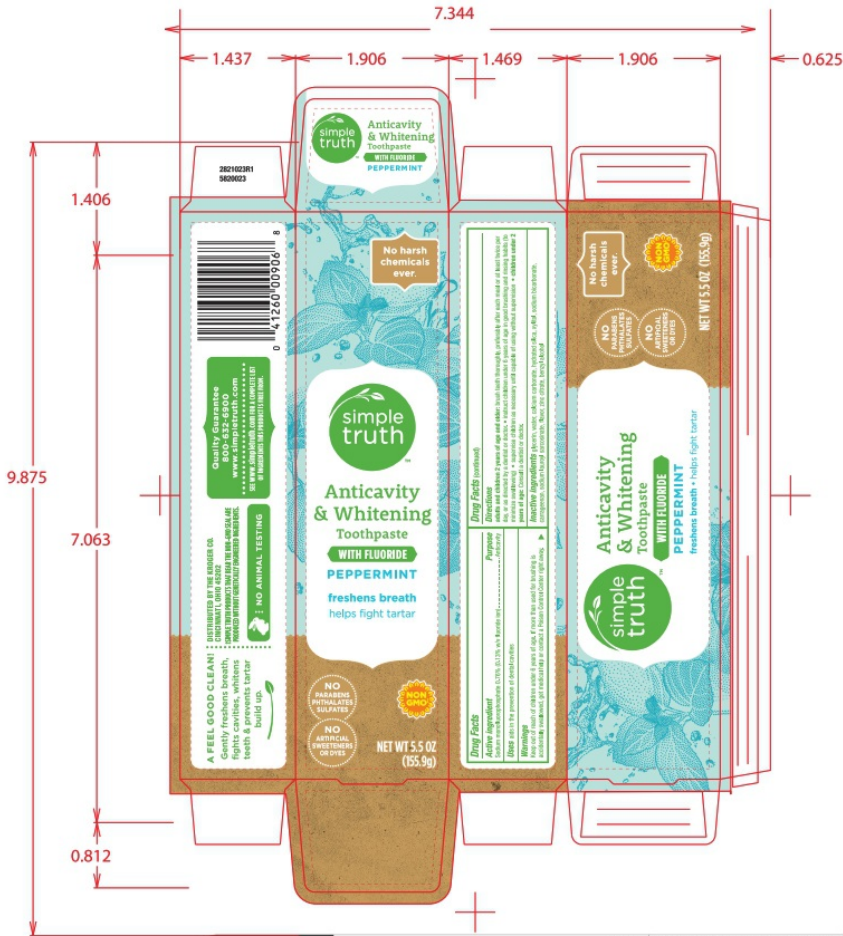
Keep out of reach of children under 6 years of age. If more than is swallowed for brushing si accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

adults and children 2 years of age and older: brush teeth thoroughly, preferably after each meal or at least twice per day, or as directed by a dentist or doctor. \* instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing) \* supervise children as necessary until capable of using without supervision \* children under 2 years of age: Consult a dentist or doctor.

glycerin, water, calcium carbonate, hydrated silica, xylitol, sodium bicarbonate, carrageenan, sodium lauroyl sarcosinate, flavor, zinc citrate, benzyl alcohol

LORNAMEAD  
1.906 X 1.469 X 7.063 - PRINTSIDE  
S170952 - 9/14/17



Ensuring visual excellence.

Prepress/Assembly

Job Description: ST\_AnticavityWhiteningToothpaste\_Peppermint\_5\_Siz\_30006\_Carton

Job Number: 19.9129

File Name: AB129K01\_00906.ap

Final Artwork Size: 9.875" x 7.344"

Operator: RND

Customer: Kroger Corporate Brands

Printer: MOD PAC CORPORATION

Vendor: Lornamead

Last Modified: 10/26/19 2:27 PM

Our SGS Quality Assurance Team has thoroughly reviewed this file. Upon receipt, please check this file carefully. Our client and its suppliers are responsible for all content, color, legal and regulatory text and product information. SGS will not be held responsible for product if the work is found to be incorrect at this stage. Should an error be found subsequent to device package approval, SGS shall be responsible only for the replacement of the artwork containing the error, and in addition, shall not be held liable for any consequential changes, charges or losses incurred as a result of any error.

Package Design Approval		
Function	Date	Signature
Packaging		
Product Development		
Regulatory Compliance		
Legal		

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New Item     Redesign     Label Info Change

**PROJECT INFO | PRODUCTION NOTES**

DATE: JANUARY 2, 2020

PROJECT: KROGER ANTICAVITY FLUORIDE CARTON

ITEM #: 2821023R1

DELINE #: S170952

SIZE: 1.906" X 1.469" X 7.063"

FILE NAME: KROGER\_ANTICAVITYFLUORIDE\_CTN\_2821023R1-0LAI

PRINTER: MODPAC

NOTES:

**APPROVALS**

CREATING \_\_\_\_\_

MARKETING \_\_\_\_\_

R&D \_\_\_\_\_

QUALITY \_\_\_\_\_

PURCHASING \_\_\_\_\_

CEO \_\_\_\_\_

# NATURAL ADULT FLUORIDE

sodium monofluorophosphate paste

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:30142-223
<b>Route of Administration</b>	DENTAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.76 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>ZINC CITRATE</b> (UNII: K72I3DEX9B)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	

### Product Characteristics

<b>Color</b>	white (Off 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:30142-223-39	1 in 1 CARTON	06/02/2020	
1		155.9 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 final	part355	06/02/2020	

**Labeler** - Kroger (006999528)

**Registrant** - Lornamead (126440440)

### Establishment

Name	Address	ID/FEI	Business Operations
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Lornamead

080046418

manufacture(30142-223)

Revised: 1/2023

Kroger