

SIMPLE TRUTH KIDS FLOURIDE- sodium monofluorophosphate paste, dentifrice
Kroger Company

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.

Kroger Kids Fluoride Toothpaste Strawberry

Drug Facts

Active ingredient

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

Purpose

Anticavity

Use

Helps protect against cavities

Warnings

Keep out of reach of children under 6 years of age. If more than used for brushing is 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 a day, or as directed by a dentist or doctor.

Children 2 to 6 years: use a pea-sized amount and supervise child's brushing and rinsing (to minimize swallowing).

☐ **Children under 2 years of age:** consult a dentist or physician.

Inactive ingredients Glycerin, Water, Calcium Carbonate, Hydrated Silica, Natural Flavor, Carrageenan, Sodium Lauroyl Sarcosinate

Other information

Store in a cool dry place. Keep tube covered when not in use.

DISTRIBUTED BY THE KROGER CO.

CINCINNATI, OHIO 45202

simple truth

KIDS' Fluoride Toothpaste

PREVENTS CAVITIES

STRAWBERRY

no artificial colors, preservatives, flavors or sweeteners

4.2 OZ (119g)



SIMPLE TRUTH KIDS FLOURIDE

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-146
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.76 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0K00R)	

SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)

Product Characteristics

Color		Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-146-79	119 g in 1 TUBE; Type 0: Not a Combination Product	02/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/25/2019	

Labeler - Kroger Company (006999528)

Registrant - Lornamead, Inc. (078584069)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead Inc.		078584069	manufacture(30 142-146)

Revised: 9/2019

Kroger Company