MCKESSON FLUORIDE- sodium monofluorophosphate paste, dentifrice McKesson Medical-Surgical

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

68599-0123

Drug Facts

Active Ingredient

Sodium Monofluorophosphate 0.76% (0.122% w/v of fluoride ion)

Purpose

Anticavity

Use

Helps protect against cavities.

Warnings

Keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, get medical help or contact a Poison Control Center immediately.

Directions

- Adults and children 2 years of age and older: Brush teeth thoroughly after meals or at least twice daily, or as directed by a dentist or physician.
- Children under 6 years of age: Use a pea-sized amount to minimize swallowing and supervise child's brushing until good habits are established.
- Children under 2 years of age: Ask a dentist or physician.

Inactive ingredients

calcium carbonate, purified water, sorbitol, hydrated silica, glycerin, sodium lauryl sulfate, flavor, tetrasodium pyrophosphate, carboxy methyl cellulose, sodium benzoate, sodium saccharin

Principal Display Panel - 1.5 oz Case Label

Mint Flavor

M^c**KESSON**

Fluoride Toothpaste

1 Tube per Box, 1.5 oz 144 Boxes Per Case

Reorder No. 16-9571



Principal Display Panel - 1.5 oz Box Label

Mint Flavor

M<u>c</u>KESSON Fluoride Toothpaste

Net Wt. 1.5 oz. (43g)



Principal Display Panel - 1.5 oz Tube Label

Mint Flavor

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Reorder No. 16-9571

Marketed By McKesson Corporation McKesson Medical-Surgical 8741 Landmark Road Richmond, VA 23228

Latex-Free

Made in Malaysia.

LP-6247-0708

MCKESSON FLUORIDE

sodium monofluorophosphate paste, dentifrice

Product Information

Droduct Type	HUMAN OTC DRUG	Itam Cada (Caurca)	NDC:68599-0123
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:00399-0123

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.43 mg in 1 g

Inactive Ingredients Ingredient Name CALCIUM CARBONATE (UNII: H0G9379FGK) WATER (UNII: 059QF0K00R) SORBITOL (UNII: 506T60A25R) HYDRATED SILICA (UNII: Y607T4G8P9) GLYCERIN (UNII: PDC6A3C0OX) SODIUM LAURYL SULFATE (UNII: 368GB5141J) SODIUM PYROPHOSPHATE (UNII: O352864B8Z) CARBOXYMETHYLCELLULOSE (UNII: 05JZ17B19X) SODIUM BENZOATE (UNII: OJ245FE5EU)

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT (MINT)	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68599- 0123-1	144 in 1 CARTON	02/17/2012	06/01/2026
1		1 in 1 BOX		
1		43 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68599- 0123-2	144 in 1 CARTON	02/17/2012	06/01/2026
2		1 in 1 BOX		
2		78 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
unapproved drug other		02/17/2012	06/01/2026

Labeler - McKesson Medical-Surgical (023904428)

Registrant - AmLion Toothpaste Mfg. Sdn. Bhd. (652244161)

Establishment				
Name	Address	ID/FEI	Business Operations	
AmLion		652244161	manufacture(68599-0123)	

Revised: 2/2024 McKesson Medical-Surgical