

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

*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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**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*

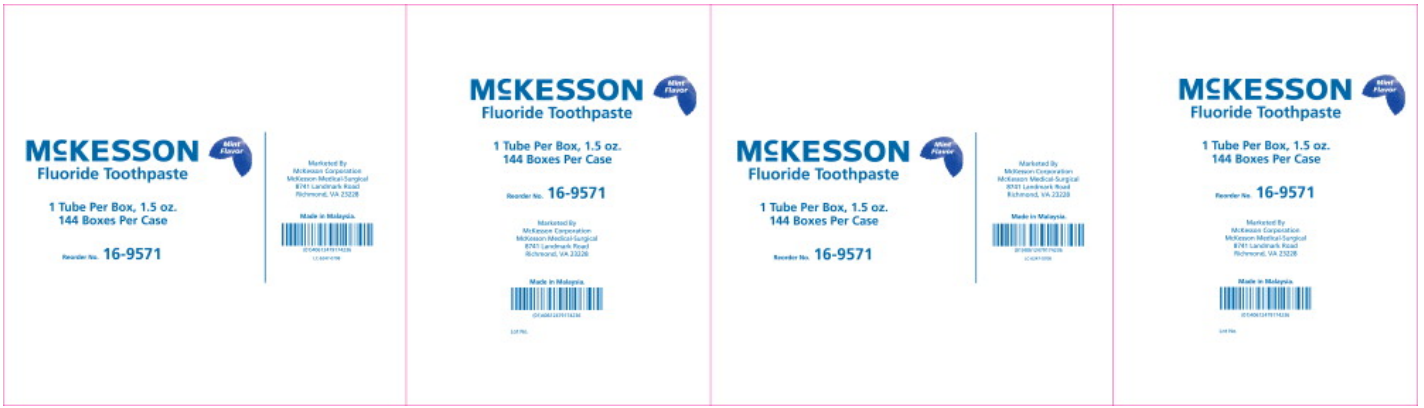
*Flavor*

**MCKESSON**  
**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

**McKESSON**  
**Fluoride Toothpaste**  
Net Wt. 1.5 oz. (43g)

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredient</b> Sodium Monofluorophosphate 0.76% (0.122% w/v of fluoride ion).....	<b>Purpose</b> Anticavity	<b>Directions</b> (continued) ▪ <b>Children under 6 years of age:</b> Use a pea-sized amount to minimize swallowing and supervise child's brushing until good habits are established. ▪ <b>Children under 2 years of age:</b> Ask a dentist or physician.	
<b>Use</b> Helps protect against cavities.		<b>Inactive ingredients</b> calcium carbonate, purified water, sorbitol, hydrated silica, glycerin, sodium lauryl sulfate, flavor, tetrasodium pyrophosphate, carboxy methyl cellulose, sodium benzoate, sodium saccharin	
<b>Warnings</b> 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.			
<b>Directions</b> ▪ <b>Adults and children 2 years of age and older:</b> Brush teeth thoroughly after meals or at least twice daily, or as directed by a dentist or physician.			

Reorder No.  
**16-9571**  
Marketed By  
McKesson Corporation  
McKesson Medical-Surgical  
8741 Landmark Road  
Richmond, VA 23228  
**Latex-Free**  
**Made in Malaysia.**  
LS-6247-0708

Principal Display Panel – 1.5 oz Tube Label

Mint  
Flavor

**MCKESSON**  
**Fluoride Toothpaste**

**Net Wt. 1.5 oz. (43g)**



<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	Reorder No. <b>16-9571</b>  Marketed By McKesson Corporation McKesson Medical-Surgical 8741 Landmark Road Richmond, VA 23228  <b>Latex-Free</b>  <b>Made in Malaysia.</b>  LP-6247-0708
<b>Active ingredient</b> Sodium Monofluorophosphate 0.76% (0.122% w/v of fluoride ion).....	<b>Purpose</b> Anticavity	<b>Directions (continued)</b> ■ <b>Children under 6 years of age:</b> Use a pea-sized amount to minimize swallowing and supervise child's brushing until good habits are established. ■ <b>Children under 2 years of age:</b> Ask a dentist or physician.	
<b>Use</b> Helps protect against cavities.		<b>Inactive ingredients</b> calcium carbonate, purified water, sorbitol, hydrated silica, glycerin, sodium lauryl sulfate, flavor, tetrasodium pyrophosphate, carboxy methyl cellulose, sodium benzoate, sodium saccharin	
<b>Warnings</b> 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.			
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**MCKESSON FLUORIDE**

sodium monofluorophosphate paste, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68599-0123
<b>Route of Administration</b>	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	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)	
<b>CARBOXYMETHYLCELLULOSE</b> (UNII: 05JZI7B19X)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (MINT)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68599-0123-1	144 in 1 CARTON	02/17/2012	
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	
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
OTC monograph final	part355	02/17/2012	

**Labeler** - McKesson Medical-Surgical (023904428)

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