

**PREMIER VALUE CAVITY PROTECTION MINT - sodium monofluorophosphate paste
Premier Value**

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.

Premier Value Cavity Protection Mint toothpaste

Active Ingredient

Sodium MonoFluoroPhosphate 0.76% (0.015% w/v fluoride ion) ...Anticavity Toothpaste

USE

Helps protect against cavities.

As with all fluoride toothpastes, keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately.

Directions

Adults and children 2 years and older Brush teeth thoroughly, preferably after each meal, or at least twice a day, or as directed by your dentist. Do not swallow.

Children under 6 years of age To minimize swallowing, use a pea-sized amount and supervise brushing until good habits are established.

Children under 2 years Ask a dentist or physician.

Principal Display Panel



AN ANTICAVITY FLUORIDE DENTIFRICE	
Drug Facts	
ACTIVE INGREDIENT	PURPOSE
Sodium MonoFluoroPhosphate 0.76% (0.15% w/v fluoride ion)	...Anticavity Toothpaste
USE: Helps protect against cavities.	
WARNINGS: As with all fluoride toothpastes, keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately.	
INACTIVE INGREDIENTS: Sorbitol, Hydrated Silica, Water, Calcium Carbonate, Glycerine, Sodium Lauryl Sulphate, Cellulose Gum, Flavor, Sodium Benzoate, Sodium Saccharin, Sodium Phosphate, Titanium Dioxide, FD&C Blue no.1.	
DISTRIBUTED BY: CHAIN DRUG CONSORTIUM, LLC., BOCA RATON, FL 33431	
Drug Facts (continued)	
DIRECTIONS	
Adults and children 2 years and older	Brush teeth thoroughly, preferably after each meal, or at least twice a day, or as directed by your dentist. Do not swallow.
Children under 6 years of age	To minimize swallowing, use a pea-sized amount and supervise brushing until good habits are established.
Children under 2 years	Ask a dentist or physician.

Inactive Ingredients

Sorbitol,Hydrated Silica,Water,Calcium Carbonate,Glycerine,Sodium Lauryl Sulphate,Cellulose Gum,Flavor,Sodium Benzoate,Sodium Saccharin, Sodium Phosphate,Titanium Dioxide,FD&C BLUE NO. 1

PREMIER VALUE CAVITY PROTECTION MINT

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:680 16-005
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (Fluoride Ion - UNII:Q80VPU408O)	SODIUM MONOFLUOROPHOSPHATE	7.6 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0KO0R)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT (Mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-005-01	21 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/08/2003	

Labeler - Premier Value (101668460)

Revised: 1/2011

Premier Value