

FRESHMAX FLUORIDE REGULAR FLAVOR- sodium monofluorophosphate paste
International Wholesale Inc

FreshMax Fluoride Toothpaste Regular Flavor

Drug Facts

Active Ingredient

Sodium Monofluorophosphate 0.76%

(Available fluoride content:1000ppm)

Purpose

Anticavity

Uses

Regular brushing with Fluoride toothpaste helps protect teeth and roots against cavities.

Warnings

Keep out of reach of children under 6 years of age.

In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions

Brush teeth thoroughly, preferable after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age to use a pea size amount. Supervise child's brushing and rinsing (to minimize swallowing.) Consult a dentist or physician. **Adults and children 2 years of age or older:Children under 6 years:Children under 2 years of age:**

Inactive Ingredients

Water, Sorbitol, Polyethylene Glycol 400, Sodium Carboxymethylcellulose, Silica, Gypsum Powder, Sodium Saccharin, Sodium Lauryl Alcohol, Flavor, Methyl Paraben, Propylparaben, Color: Bright Blue.

Other Information:

Lot No. & Expiration Date: See box or crimp of tube.

Package Labeling:



FRESHMAX FLUORIDE REGULAR FLAVOR

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52862-500
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	76 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52862-500-00	1 in 1 BOX	02/27/2017	
1		181 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 Drug	M021	02/27/2017	

Labeler - International Wholesale Inc (161872676)

Revised: 10/2023

International Wholesale Inc