

FIREFLY PEDIATRIC- sodium monofluorophosphate paste
Dr. Fresh, LLC

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.

FireFly Pediatric Kit

Active Ingredient

Sodium Monofluorophosphate 0.76%

Purpose

Anti-Cavity Toothpaste

Use: Helps prevent against cavities

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

Warnings: If you accidentally swallow more than used for brushing, get medical help or contact a Poison Control Center immediately.

Directions: adults and children 2yrs.and older: brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist. To minimize swallowing use a pea sized amount in children under 6. Supervise children's brushing until good habits are established. Children under 2 yrs.:ask a dentist

Inactive Ingredients: Sorbitol, Silica, Water, Sodium Lauryl Sulfate, Flavor, PEG-32, Mica, Sodium Carboxy Methyl Cellulose, Saccharin, Trisodium Phosphate, FDandC Blue No. 1, Calcium Glycerophosphate

Questions? Call 1-866-373-7374

www.drfresh.com

DR.Fresh

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FIREFLY

Kids Comply With Firefly!

Pediatric Kit

Premium Zip Pouch

Contains:

- FireFly Lightup Timer Toothbrush
- FireFly Bubble Gum Toothpaste
- FireFly Flossers
- Toothbrush Cap

Be sure to brush 1 minute on top teeth and 1 minute on bottom teeth

Comments? Questions?

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Pediatric Kit

Premium Zip Pouch

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Join FireFly® on Facebook for tips, updates and contests!
facebook.com/FireFlyToothbrush

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FIREFLY®

Drug Facts

Active Ingredient	Purpose
Sodium monofluorophosphate 0.70%	Anti-Cavity Toothpaste

Uses: Helps prevent 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 yrs. & older: brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist. To minimize swallowing use a pea-sized amount in children under 6. Supervise children's brushing until good habits are established. Children under 2 yrs: ask a dentist

Inactive Ingredients: Sorbitol, Silica, Water, Sodium Lauryl Sulfate, Flavor, PEG-32, Mica, Sodium Carboxy Methyl Cellulose, Saccharin, Trisodium Phosphate, FD&C Blue No. 1, Calcium Glycero-phosphate

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 US Patent No. 3490247 S, Canada Patent No. CA 2455748, China Patent No. ZL200410002383.5
 US Patent No. 6,985,307, US Patent No. D304,187
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Drug Facts		Drug Facts (continued)	
Active Ingredient	Purpose	pea sized amount in children under 6. Supervise children's brushing until good habits are established. Children under 2 yrs.: ask a dentist	
Sodium monofluorophosphate 0.76%	Anti-Cavity Toothpaste	Inactive Ingredients: Sorbitol, Silica, Water, Sodium Lauryl Sulfate, Flavor, PEG-32, Mica, Sodium Carboxy Methyl Cellulose, Saccharin, Trisodium Phosphate, FD&C Blue No. 1, Calcium Glycerophosphate	
Use: Helps prevent against cavities		Questions? Call 1-866-373-7374	
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.		www.drfresh.com	
Directions: adults and children 2 yrs. & older: brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist . To minimize swallowing use a -			



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- Toothbrush Cap



Be sure to brush 1 minute on top teeth and 1 minute on bottom teeth

Comments? Questions?
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MADE IN CHINA





FIREFLY PEDIATRIC

sodium monofluorophosphate paste

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:64893-802

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SACCHARIN (UNII: FST467XS7D)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CALCIUM GLYCEROPHOSPHATE (UNII: XWV9Z12C1C)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64893-802-00	1 in 1 POUCH	08/17/2011	
1		28 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	08/17/2011	

Labeler - Dr. Fresh, LLC (117376803)

Revised: 11/2021

Dr. Fresh, LLC