

AQUAFRESH KIDS CAVITY PROTECTION- sodium monofluorophosphate paste
GlaxoSmithKline Consumer Healthcare Holdings (US) 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.

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.84% (0.15% w/v fluoride ion)

Purpose

Anticavity

Use

- aids in the prevention of dental cavities.

Warnings

When using this product,

if irritation occurs discontinue use.

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

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **adults and children 2 years and older:**
 - apply toothpaste onto a toothbrush.
 - brush teeth thoroughly, preferably after each meal or at least twice a day, and not more than 3 times a day, or as directed by a dentist or doctor. Minimize swallowing. Spit out after brushing.
 - to minimize swallowing for children under 6 years of age, use a pea-sized amount and supervise brushing and rinsing until good habits are established.
- **children under 2 years of age:** Consult a dentist or doctor.

Other information

- Do not store above 25°C (77°F)

Inactive ingredients (bubble mint)

water, sorbitol, calcium carbonate, hydrated silica, glycerin, PEG-8, flavor, titanium dioxide, sodium

lauryl sulfate, cellulose gum, sodium bicarbonate, sodium saccharin, calcium carrageenan, red 30, blue 1

Questions or comments?

Call toll-free **1-800-897-5623**

Principal Display Panel

NDC 0135-0619-01

Aquafresh®

Fluoride Toothpaste

kids

Cavity Protection

2+ years

Sugar Acid Protection **

From Fluoride

BUBBLE MINT

ADA Accepted

American Dental Association®

NET WT 4.6 OZ (130.4 g)

Aquafresh toothpaste fights cavities with fluoride...

freshens breath...

and has a great bubble mint taste, in one complete toothpaste.

***With Sugar Acid Protection provided by fluoride, which strengthens enamel, creating a shield that protects the tooth surface against sugar acid attack.*

ALWAYS FOLLOW THE LABEL

This product contains no sugar, like all ADA-accepted toothpastes.

Helps prevent cavities.

Note: If pump doesn't work, hold button down and firmly push up inside base.

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Warren, NJ 07059

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gsk

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AQUAFRESH KIDS CAVITY PROTECTION

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0619
Route of Administration	DENTAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)			FLUORIDE ION	1.10 mg in 1 g
Inactive Ingredients				
Ingredient Name				Strength
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
CALCIUM CARBONATE (UNII: H0G9379FGK)				
HYDRATED SILICA (UNII: Y6O7T4G8P9)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
CARRAGEENAN CALCIUM (UNII: 5C4SQ0541D)				
D&C RED NO. 30 (UNII: 2S42T2808B)				
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0619-01	130.4 g in 1 CANISTER; Type 0: Not a Combination Product	09/01/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	09/01/2017		

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

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GlaxoSmithKline Consumer Healthcare Holdings (US) LLC