

**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.*

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**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:**
  - o apply toothpaste onto a toothbrush.
  - o 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.
  - o 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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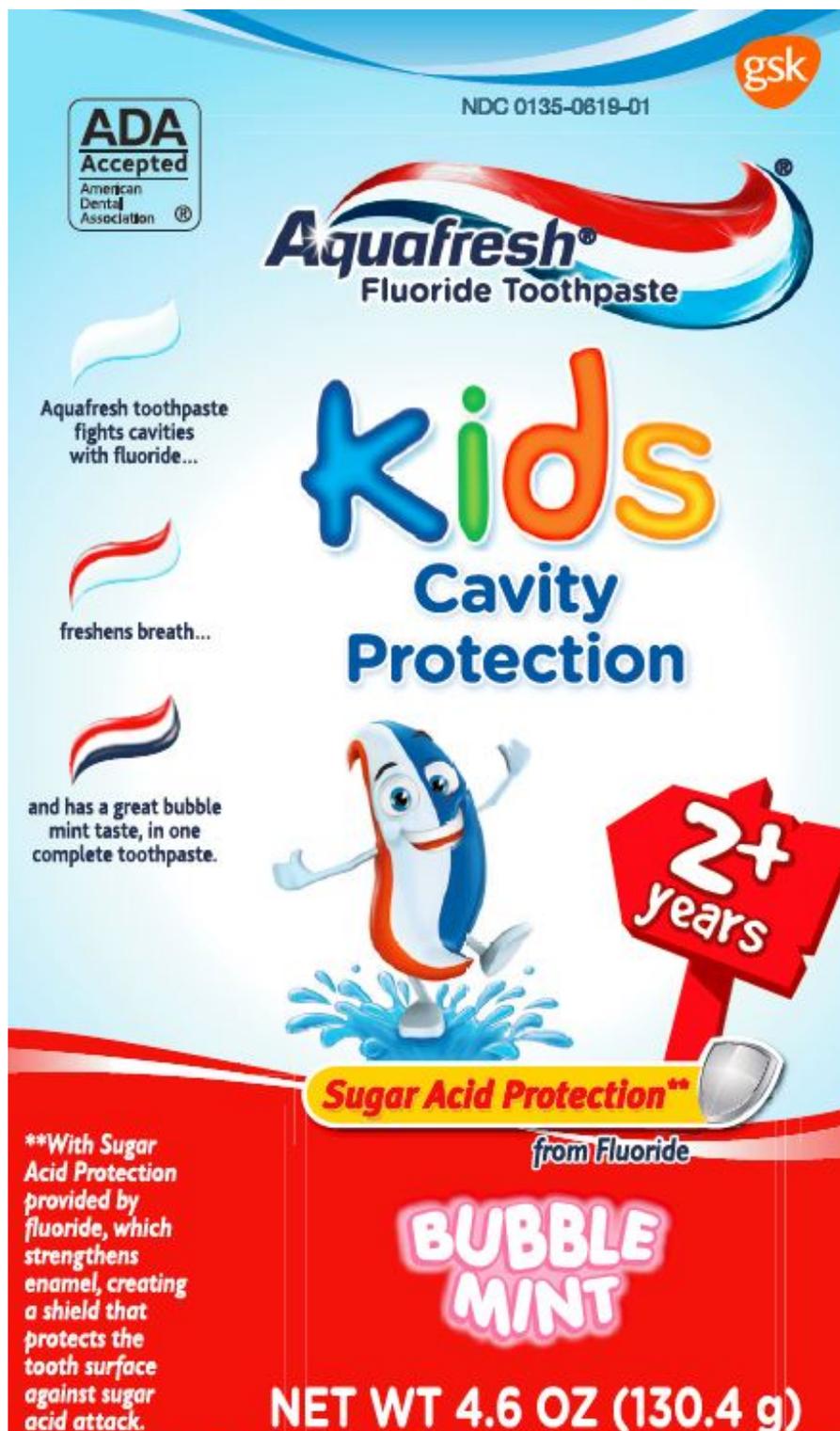
Distributed by:

GSK Consumer Healthcare

Warren, NJ 07059

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The image shows the packaging for Aquafresh Kids Cavity Protection Bubble Mint Fluoride Toothpaste. The top left corner features the ADA Accepted logo (American Dental Association). The top right corner has the GSK logo and the NDC number 0135-0819-01. The brand name 'Aquafresh' is written in a stylized font with a red, white, and blue wave graphic behind it, followed by 'Fluoride Toothpaste'. The word 'Kids' is in large, colorful letters (blue, green, orange, yellow), and 'Cavity Protection' is in blue. A cartoon character of a tooth with a face and arms is jumping out of a splash of water. To the right of the character is a red sign that says '2+ years'. Below the character is a yellow banner that says 'Sugar Acid Protection\*\*' with a shield icon, and 'from Fluoride' below it. The flavor 'BUBBLE MINT' is written in large, pink, bubbly letters. At the bottom, it says 'NET WT 4.6 OZ (130.4 g)'. On the left side, there are three wavy graphics with text: 'Aquafresh toothpaste fights cavities with fluoride...', 'freshens breath...', and 'and has a great bubble mint taste, in one complete toothpaste.' A red banner at the bottom left contains the text: '\*\*With Sugar Acid Protection provided by fluoride, which strengthens enamel, creating a shield that protects the tooth surface against sugar acid attack.'

ADA Accepted  
American Dental Association

NDC 0135-0819-01

gsk

Aquafresh®  
Fluoride Toothpaste

Aquafresh toothpaste  
fights cavities  
with fluoride...

freshens breath...

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

**Kids**  
Cavity  
Protection

2+  
years

Sugar Acid Protection\*\*  
from Fluoride

BUBBLE  
MINT

NET WT 4.6 OZ (130.4 g)

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

AQUAFRESH KIDS CAVITY PROTECTION

sodium monofluorophosphate paste

## Product Information

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

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.10 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>CARRAGEENAN CALCIUM</b> (UNII: 5C4SQ0541D)	
<b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0135-0619-01	130.4 g in 1 CANISTER; Type 0: Not a Combination Product	09/01/2017	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part355	09/01/2017	

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

