

AQUAFRESH EXTREME CLEAN PURE BREATH ACTION- sodium fluoride paste
Haleon US Holdings LLC

Drug Facts

Active ingredient

Sodium fluoride 0.25% (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 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 of age 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

- store below 30°C (86°F)

Inactive ingredients

water, hydrated silica, sorbitol, glycerin, PEG-8, sodium lauryl sulfate, flavor, xanthan gum, titanium dioxide, cocamidopropyl betaine, sodium citrate, sodium saccharin, zinc

chloride, iron oxides, red 30, blue 1

Questions or comments?

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

Principal Display Panel

NDC 0135-0604-01

Aquafresh®

triple protection®

fluoride toothpaste

pure breath action

Sugar Acid Protection**

from Fluoride

EXTREME CLEAN®

WITH MICRO-ACTIVE FOAMING ACTION + WHITENING

for 80% cleaner, purer breath*

NET WT 5.6 OZ (158.8g)

fresh mint

Aquafresh® Extreme Clean® Pure Breath Action toothpaste creates micro-active foam which seeks out hard to reach places and rinses clear to leave your teeth clean and smooth. It neutralizes bad breath odors for 80% cleaner, purer breath.* Take the Feeling of Clean to the Extreme!®

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

triple protection®

- *healthy gums†*
- *strong teeth*
- *fresh breath*

†with twice daily brushing

*immediately after brushing versus a zinc free toothpaste

ALWAYS FOLLOW THE LABEL

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GSK Consumer Healthcare

Warren, NJ 07059

1-800-897-5623

105483XA



AQUAFRESH EXTREME CLEAN PURE BREATH ACTION

sodium fluoride paste

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0604 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) | FLUORIDE ION | 1.15 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| HYDRATED SILICA (UNII: Y607T4G8P9) | |
| SORBITOL (UNII: 506T60A25R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| ZINC CHLORIDE (UNII: 86Q357L16B) | |
| FERRIC OXIDE YELLOW (UNII: EX43802MRT) | |
| D&C RED NO. 30 (UNII: 2S42T2808B) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |

Product Characteristics

| | | | |
|-------|--|-------|--|
| Color | | Score | |
|-------|--|-------|--|

| | | | |
|-----------------|-------------------|---------------------|--|
| Shape | | Size | |
| Flavor | MINT (fresh mint) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0135-0604-01 | 1 in 1 CARTON | 06/01/2016 | |
| 1 | | 158.8 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 | M022 | 06/01/2016 | |

Labeler - Haleon US Holdings LLC (079944263)