

**AQUAFRESH CAVITY PROTECTION- sodium fluoride paste**  
**AQUAFRESH EXTRA FRESH PLUS WHITENING- sodium fluoride paste**  
**AQUAFRESH MULTI ACTION WHITENING- sodium fluoride paste**  
**AQUAFRESH ULTIMATE WHITE- sodium fluoride paste**  
**Haleon US Holdings LLC**

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**Drug Facts**

***Active ingredient (Cavity Protection, Extra Fresh +Whitening, Multi Action Whitening)***

Sodium fluoride 0.25% (0.15% w/v fluoride ion)

***Active ingredient (ultimate white)***

Sodium fluoride 0.24% (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 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 (Cavity Protection)***

water, hydrated silica, sorbitol, glycerin, sodium lauryl sulfate, xanthan gum, flavor, titanium dioxide, PEG-8, sodium saccharin, carrageenan, red 30, blue 1

### ***Inactive ingredients (Extra Fresh +Whitening)***

water, hydrated silica, sorbitol, glycerin, sodium lauryl sulfate, flavor, xanthan gum, titanium dioxide, PEG-8, sodium saccharin, carrageenan, red 30, blue 1

### ***Inactive ingredients (Multi Action Whitening)***

water, hydrated silica, sorbitol, glycerin, PEG-8, sodium lauryl sulfate, xanthan gum, flavor, titanium dioxide, cocamidopropyl betaine, sodium citrate, sodium saccharin, zinc chloride, red 30, blue 1

### ***Inactive ingredients (ultimate white)***

water, hydrated silica, sorbitol, glycerin, pentasodium triphosphate, PEG-8, sodium lauryl sulfate, titanium dioxide, flavor, xanthan gum, sodium hydroxide, sodium saccharin, red 30, blue 1

### ***Questions or comments?***

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

### **Principal Display Panel**

**NDC 0135-0590-01**

***Aquafresh***<sup>®</sup>

*fluoride toothpaste*

*triple protection*<sup>®</sup>

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

**cavity protection**

**Sugar Acid Protection\*\***

*from Fluoride*

**cool mint**

NET WT 5.6 OZ (158.8 g)

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

*\*with twice daily brushing*

**ALWAYS FOLLOW THE LABEL**

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**GSK** Consumer Healthcare

Warren, NJ 07059

Made in Taiwan

**1-800-897-5623**

105263XA



**Principal Display Panel**

**NDC 0135-0591-01**

**Aquafresh®**

*fluoride toothpaste*

*triple protection®*

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

**extra fresh +whitening**

**Sugar Acid Protection\*\***

*from Fluoride*

**fresh mint**

NET WT 5.6 OZ (158.8 g)

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

*\*with twice daily brushing*

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**GSK** Consumer Healthcare

Warren, NJ 07059

**1-800-897-5623**

105282XA



**Principal Display Panel**

**NDC 0135-0594-01**

***Aquafresh***<sup>®</sup>

*fluoride toothpaste*

*triple protection*<sup>®</sup>

**WHITENING**

**MULTI ACTION**

***Sugar Acid Protection***<sup>\*\*</sup>

*from Fluoride*

NET WT 5.6 OZ (158.8 g)

*cavity protection*

*healthy gums*<sup>\*</sup>

*breath*

*great taste*

*whitening†*

*enamel*

Invigorating Mint

**cavity protection**

**healthy gums\***

**fresh breath**

**great taste**

**removes surface stains**

**enamel strengthening**

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

*\*with twice daily brushing*

*†whitens by removing surface stains*

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**GSK** Consumer Healthcare

Warren, NJ 07059

105384XA



**Principal Display Panel**

**NDC 0135-0592-01**

**Aquafresh**<sup>®</sup>

*fluoride toothpaste*

*triple protection*<sup>®</sup>

**ultimate white**

**Sugar Acid Protection\*\***

from Fluoride  
with whitening action

**frost mint**

**NET WT 6.0 OZ (170.1 g)**

*Aquafresh® Ultimate White toothpaste gently polishes your teeth, lifts away stains and helps to prevent new stains appearing.*

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

- **healthy gums†**
  - **strong teeth**
  - **fresh breath**
- †with twice daily brushing

**ALWAYS FOLLOW THE LABEL**

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**GSK** Consumer Healthcare, Warren, NJ 07059

**1-800-897-5623**

105287XA



**AQUAFRESH CAVITY PROTECTION**

sodium fluoride paste

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0590
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.15 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)	
<b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (cool mint)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0590-01	1 in 1 CARTON	10/01/2016	
1		158.8 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0590-04	2 in 1 CARTON	11/01/2016	
2		158.8 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0135-0590-02	1 in 1 CARTON	11/01/2016	
3		85 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	10/01/2016	

## AQUAFRESH EXTRA FRESH PLUS WHITENING

sodium fluoride paste

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0591
<b>Route of Administration</b>	DENTAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.15 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)	
<b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (fresh mint)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0135-0591-01	1 in 1 CARTON	10/01/2016	
1		158.8 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0591-02	1 in 1 CARTON	11/01/2016	
2		85.1 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing</b>	<b>Application Number or Monograph</b>	<b>Marketing Start</b>	<b>Marketing End</b>
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Category	Citation	Date	Date
OTC Monograph Drug	M022	05/09/2014	

## AQUAFRESH MULTI ACTION WHITENING

sodium fluoride paste

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0594
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.15 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3011KX)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>ZINC CHLORIDE</b> (UNII: 86Q357L16B)	
<b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0594-01	1 in 1 CARTON	01/31/2017	06/30/2018
1		158.8 g in 1 TUBE; Type 0: Not a Combination		

Product			
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	01/31/2017	06/30/2018

**AQUAFRESH ULTIMATE WHITE**  
sodium fluoride paste

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0592
Route of Administration	DENTAL		

<b>Active Ingredient/Active Moiety</b>			
Ingredient Name	Basis of Strength	Strength	
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 mg	in 1 g

<b>Inactive Ingredients</b>			
Ingredient Name	Strength		
<b>WATER</b> (UNII: 059QF0KO0R)			
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)			
<b>SORBITOL</b> (UNII: 506T60A25R)			
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)			
<b>SODIUM TRIPOLYPHOSPHATE ANHYDROUS</b> (UNII: 9SW4PFD2FZ)			
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)			
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)			
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)			
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)			
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)			
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)			
<b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)			
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)			

<b>Product Characteristics</b>			
Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0592-01	1 in 1 CARTON	01/31/2017	08/31/2020
1		170.1 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	01/31/2017	08/31/2020

**Labeler** - Haleon US Holdings LLC (079944263)

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Haleon US Holdings LLC