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

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*** **®**

fluoride toothpaste

triple protection ®

- *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

GSKConsumer 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

ALWAYS FOLLOW THE LABEL

GSKConsumer Healthcare

Warren, NJ 07059

1-800-897-5623

105282XA

Principal Display Panel

NDC 0135-0594-01

- ***Aquafresh*** **®**

fluoride toothpaste

triple protection ®

WHITENING

MULTI ACTION

Sugar Acid Protection**

from Fluoride

NET WT 5.6 OZ (158.8 g)

cavity protection

*healthy gums**

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 shidl that protects the tooth surface against sugar acid attack.*

**with twice daily brushing*

†whitens by removing surface stains

ALWAYS FOLLOW THE LABEL

GSKConsumer Healthcare

Warren, NJ 07059

105384XA

Principal Display Panel

NDC 0135-0592-01

- ***Aquafresh*** **®**

fluoride toothpaste

triple protection ®

ultimate white

Sugar Acid Protection**

from Fluoride

with whitening action

frost mint

NET WT6.0 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 attach.***

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

ALWAYS FOLLOW THE LABEL

GSKConsumer Healthcare, Warren, NJ 07059

1-800-897-5623

105287XA

AQUAFRESH CAVITY PROTECTION

sodium fluoride paste

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0590
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.15 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SORBITOL (UNII: 506T60A25R)	

GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	MINT (cool mint)	**Imprint Code**	
Contains			

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		
4	NDC:0135-0590-05	3 in 1 CARTON	02/28/2021	
4		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	10/01/2016	

AQUAFRESH EXTRA FRESH PLUS WHITENING

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0591

Route of Administration	DENTAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
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:0135-0591-01	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

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End 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**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.15 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
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)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FD&C BLUE NO. 1 (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		

Marketing Information

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

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0592
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM TRIPOLYPHOSPHATE ANHYDROUS (UNII: 9SW4PFD2FZ)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FD&C BLUE NO. 1 (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:0135-0592-01	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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