

AQUAFRESH WHITENING INTENSE WHITE- sodium fluoride paste
AQUAFRESH WHITENING WHITE AND SHINE- sodium fluoride paste
Haleon US Holdings LLC

Drug Facts

Purpose

Oral, helps prevents cavity

Directions

Brush teeth twice a day, and no more than three times, avoid swallowing. Spit out after brushing.

Warnings

Always follow the label. Do not use in children under 7 years of age.

Like other toothpastes, discontinue use if irritation or adverse reaction occurs. Consult a dentist if using fluoride supplements.

Store below 30°C.

Keep out of reach of children.

Active ingredient

Sodium fluoride (sodium fluoride 0.15%) (1150 ppm of ion).

Contains Sodium Fluoride

Inactive ingredients

Water; Sorbitol; Hydrated Silica; Glycerin; Pentasodium Triphosphate; PEG-8; Sodium Lauryl Sulfate; Flavor*; Titanium Dioxide; Alumina; Xanthan Gum; Cocamidopropyl betaine; Carrageenan; Sodium Saccharin; Sodium Hydroxide; Polyethylene; CI42090; CI73360.

*Contains d-limonene.

Principal Display Panel

NDC 0135-0613-01

***Aquafresh*®**

whitening

Fluoride toothpaste

triple protection ®

New Formula

white & shine

Brighter teeth in 1 week*

NET WT 121.9g (4.3oz)

Brighter teeth in just 1 week, thanks to the toothpaste Aquafresh White & Shine. Clinically proven*. Helps keep your teeth whiter and brighter for longer. Lasting whitening.

Protection to keep your mouth healthy and happy

*Compared to a standard toothpaste, with regular brushing

Made in the United States of America by: GlaxoSmithKline LLC, East Durham, NY 12423. Aquafresh® is a trademark of the GlaxoSmithKline group of companies.

Imported and distributed by:

GlaxoSmithKline Argentina S.A., C. Casares 3690, Victoria, Bs.As., Argentina. Legajo N° 6557. M.S. Resol. N° 155/98. For questions: 0800 888-6006

GlaxoSmithKline Brasil Ltda., Est. dos Bandeirantes, 8464, Rio de Janeiro, RJ. CNPJ33.247.743/0001-10. AFE: 2000086 Proc.: 25351080153201313. SAC 0800 021 15 29.

GlaxoSmithKline Chile Farmaceutica Ltda., Lo Boza 107, Modulo A-6, Pudahuel, Santiago, Chile. Reg. I.S.P. N° 299C-38/13. For questions: 800382900.

Andean Region: Hansa Ltda., La Paz, Bolivia.

GlaxoSmithKline Colombia S.A., Bogota, D.C., Colombia. For questions: 01-8000-118686.

GlaxoSmithKline Ecuador S.A., Quito, Ecuador.

GlaxoSmithKline Peru S.A., Av. Javier Prado Oeste 995, Peru. RUC 20100123682.

GlaxoSmithKline Costa Rica S.A., 400 mts. East of the Circle La Bandera, Sabanilla highway, San Jose, Costa Rica. Tel: 506 22066000.

GlaxoSmithKline Paraguay S.A., G. Aranda 333, Paraguay. Distributed by Helsecke y Cia. S.A.C.I. Req. Sanit. N°.

GlaxoSmithKline Uruguay S.A., Salto 1105 Montevideo, Uruguay. Imp. N°10. Ley 15443. Reg. MSP N°.

GlaxoSmithKline Venezuela C.A., Caracas, Venezuela. Registered under MPPS bajo NSO-PC-E-45.970-VE. RIF: J-00021492-1. **Panama. Nicaragua. El Salvador. Honduras. Guatemala. Dominican Rep.**

102938XA



Principal Display Panel

NDC 0135-0614-01

Aquafresh®

whitening

Fluoride toothpaste

triple protection®

New Formula

intense white

whiter teeth that last longer*

NET WT 121.9g (4.3oz)

Whiter teeth that last longer*. Smile with confidence in your visibly whiter teeth for longer-result clinically proven by Aquafresh Intense White*. Contains small particles to clean and visibly whiten your teeth. Creates a protective barrier that helps prevent movement and new stains.

Protection to keep your mouth healthy and happy

*Compared to a standard toothpaste, with regular brushing, as assessed by dentists.

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We value your opinion

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AQUAFRESH WHITENING INTENSE WHITE

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0614
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII: Q80VPU4080)	FLUORIDE ION	1.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	

SODIUM TRIPOLYPHOSPHATE ANHYDROUS (UNII: 9SW4PFD2FZ)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
XANTHAN GUM (UNII: TTV12P4NEE)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0614-01	1 in 1 CARTON	06/27/2016	
1		121.9 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
Export only		06/27/2016	

AQUAFRESH WHITENING WHITE AND SHINE

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0613
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	1.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	

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Labeler - Haleon US Holdings LLC (079944263)