

**AQUAFRESH WHITENING WHITE AND SHINE- sodium fluoride paste**  
**AQUAFRESH WHITENING INTENSE WHITE- sodium fluoride paste**  
**GlaxoSmithKline Consumer Healthcare Holdings (US) LLC**

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**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.**

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**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 WHITE AND SHINE

sodium fluoride paste

### Product Information

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	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: LM26O6933)	
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:0135-0613-01	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 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:Q80VPU408O)	FLUORIDE ION	1.5 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
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)	
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**Labeler** - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 6/2016

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC