BIOTENE FRESH MINT ORIGINAL- sodium fluoride paste
BIOTENE GENTLE MINT- sodium fluoride paste
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Drug Facts

Active ingredient

Sodium Fluoride (0.15% w/v fluoride ion)

Purpose

Anticavity

Use

aids in the prevention of dental cavities

Warnings

Keep out of reach of children 12 years of age and under (Fresh Mint and Gentle Mint)

If you accidentally swallow more than used for brushing, get medical help or contact a Poison Control Center right away. Do not use if you are allergic to any of the ingredients.

Keep out of reach of children 12 years of age and under. (PBF)

If you accidentally swallow more than used for brushing, get medical help or contact a Poison Control Center right away. If symptoms of a dry mouth persist, consult a healthcare professional. Do not use if you are allergic to any of the ingredients.

Directions

Adults and children over 12 years

- apply toothpaste onto a soft bristle toothbrush
- brush thoroughly after meals or at least twice a day or use as directed by a dentist or physician.

Children 12 years and underask a dentist or physician. Once recommended, to minimize swallowing for children under 6, use a pea-sized amount and supervise brushing until good habits are established.

Other information

store below 25°C (77F°)

Inactive ingredients (Fresh Mint Original)

Water, Sorbitol, Hydrated Silica, Glycerin, PEG-8, Cocamidopropyl Betaine, Xanthan Gum, Flavor, Sodium Saccharin, Sucralose, Titanium Dioxide, Sodium Hydroxide

Inactive ingredients (Gentle Mint)

Water, Sorbitol, Hydrated Silica, Glycerin, PEG-8, Cocamidopropyl Betaine, Xanthan Gum, Flavor, Sodium Saccharin, Sucralose, Sodium Hydroxide, D&C Yellow #10, FD&C Blue #1

Questions or comments?

call toll-free **1-800-922-5856**weekdays

Principal Display Panel

NDC 0135-0557-01

biotene®

FLUORIDE TOOTHPASTE

GENTLE FORMULA

SPECIALLY FORMULATED TO NOT IRRITATE

FRESH MINT ORIGINAL

NET WT 4.3 OZ (121.9g)

FROM THE MAKERS OF BIOTENE

#1 DENTIST & HYGIENTIST RECOMMENDED BRAND FOR DRY MOUTH SYMPTOMS

HELPS MAINTAIN ORAL ENVIRONMENT

- HELPS FRESHEN BAD BREATH
- SLS FREE
- BALANCED PH
- GENTLE FORMULA
- ESSENTIAL FLUORIDE TOOTH PROTECTION

Also look for other **biotene ®**products including **biotene ®Oral Rinses, biotene ®oralbalance Gel,** and **biotene ®Mouth Spray.**

ALWAYS FOLLOW THE LABEL

This product contains no Sodium Lauryl Sulfate (SLS)

Biotene, oralbalanceand graphic elements are trademarks of the GSK group of companies.

www.biotene.com

Distributed by:

GlaxoSmithKline

Consumer Healthcare, L.P.

Moon Township, PA 15108

102875XC

Principal Display Panel

NDC 0135-0558-01

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Consumer Healthcare, L.P.

Moon Township, PA 15108

102874XC

BIOTENE FRESH MINT ORIGINAL

sodium fluoride paste

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0557
Route of Administration	ORAL		

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)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor	MINT (Fresh Mint)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0135-0557-01	1 in 1 CARTON	07/15/2013	
1		121.9 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0557-02	1 in 1 CARTON	07/15/2013	
2		19.8 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	07/15/2013	

BIOTENE GENTLE MINT

sodium fluoride paste

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0558
Route of Administration	ORAL		

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)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	green	**Score**	
Shape		**Size**	
Flavor	MINT (Gentle Mint)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0558-01	1 in 1 CARTON	07/15/2013	
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
OTC Monograph Drug	M022	07/15/2013	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 11/2023 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC