

BIOTENE FRESH MINT ORIGINAL- sodium fluoride paste

BIOTENE GENTLE MINT- sodium fluoride paste

BIOTENE PBF- sodium fluoride paste

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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 under ask 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

Inactive ingredients (PBF)

Water, Sorbitol, Hydrated Silica, Glycerin, PEG-8, Cocamidopropyl Betaine, Xanthan Gum, Flavor, Sodium Saccharin, Sucralose, Sodium Hydroxide, Dextranase, 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, oralbalance and graphic elements are trademarks of the GSK group of companies.

www.biotene.com

Distributed by:

GlaxoSmithKline

Consumer Healthcare, L.P.

Moon Township, PA 15108

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Principal Display Panel

NDC 0135-0558-01

biotene®

FLUORIDE TOOTHPASTE

GENTLE FORMULA

SPECIALLY FORMULATED TO NOT IRRITATE

GENTLE MINT

NET WT 4.3 OZ (121.9g)

FROM THE MAKERS OF BIOTENE

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Principal Display Panel

NDC 0135-0559-01

biotene®

DRY MOUTH

PBF® FLUORIDE TOOTHPASTE

GENTLE FORMULA

DESIGNED TO NOT IRRITATE A DRY MOUTH

PLAQUE-BIOFILM LOOSENING FORMULA

NET WT 4.3 OZ (121.9g)

#1 Dentist & Hygienist Recommended Brand for Dry Mouth

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® orallbalance Gel**, **biotene® Mouth Spray** and **biotene® Gum**.

ALWAYS FOLLOW THE LABEL

This product contains no Sodium Lauryl Sulfate (SLS)

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GENTLE FORMULA

biotene®

DRY MOUTH
PBF® FLUORIDE
TOOTHPASTE

DESIGNED TO NOT IRRITATE A DRY MOUTH

PLAQUE-BIOFILM LOOSENING FORMULA

NET WT 4.3 OZ (121.9 g)

NDC 0135-0559-01

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DENTIST & HYGIENIST RECOMMENDED BRAND FOR DRY MOUTH

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: 5OCF3011KX)	
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 final	part355	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: HBR47K3TBD)	

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 final	part355	07/15/2013	

BIOTENE PBF

sodium fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0559
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: HBR47K3TBD)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	MINT	Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0559-01	1 in 1 CARTON	07/15/2013	07/31/2016
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
OTC monograph final	part355	07/15/2013	07/31/2016

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

Revised: 12/2016

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC