BIOTENE- sodium monofluorophosphate paste
Haleon US Holdings LLC

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.76% (0.14% 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 bushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **adults and children 2 years of age and older:**
    - apply toothpaste onto a toothbrush
    - brush teeth thoroughly, preferable 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. Minimizing swallowing. Spit out after brushing.
    - to minimize swallowing for children under 6 years of age, use a pea-sized amoun and supervise brushing and rinsing until good habits are established.
- **children under 2 years of age:** Consult a dentist or doctor.

Other information

store at or below 25ºC (77ºF)

Inactive ingredients

sorbitol, glycerin, calcium pyrophosphate, water, hydrated silica, xylitol, silica, hydroxyethyl cellulose, isoceteth-20, cellulose gum, flavor, sodium benzoate, sodium lactate.

Questions or comments?

Call toll-free **1-800-922-5856**

Additional information

This product contains no Sodium Lauryl Sulfate (SLS)

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Distributed by:

GSK Consumer Healthcare

Warren, NJ 07059

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Questions or Comments?

1-800-922-5856

Principal Display Panel

NDC 0135-0577-01

biotene®

Fluoride Toothpaste

SPECIALLY FORMULATED TO NOT IRRITATE

Helps prevent cavities & strengthen teeth

Gentle Formula

GENTLE MINT

NET WT 4.3 OZ (121.9g)

1000114 Front Carton

BIOTENE

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0577
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.4 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CALCIUM PYROPHOSPHATE (UNII: X69NU20D19)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
XYLITOL (UNII: VCQ006KQ1E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
ISOCETETH-20 (UNII: O020065R7Z)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CALCIUM LACTATE ANHYDROUS (UNII: 2URQ2N32W3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0577-01	1 in 1 CARTON	09/01/2016	
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 Drug	M022	09/01/2016	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 11/2024 Haleon US Holdings LLC