

NATURAL FLUORIDE FRESH MINT CAVITY PROTECTION WHITENING FRESH BREATH- sodium fluoride paste, dentifrice
Tom's of Maine, Inc.

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.

Natural Fluoride Toothpaste, Fresh Mint cavity protection / whitening / fresh breath

Drug Facts

Active ingredient

Sodium fluoride 0.24% (0.15% w/v fluoride ion)

Purpose

Anticavity

Use

helps protect against cavities

Warnings

Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or dial (412) 390-3381 right away (Poison Control Center).

Directions

adults and children 2 years of age and older	brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician.
children 2 to 6 years	use only a pea-sized amount and supervise child's brushing and rinsing (to minimize swallowing)
children under 2 years	ask a dentist or physician

Inactive ingredients

hydrated silica, water, sorbitol, glycerin, xylitol, sodium lauryl sulfate, natural flavor¹, xanthan gum, titanium dioxide, carrageenan.

1 Peppermint oil and other natural flavor

Questions?

1-800-FOR-TOMS (1-800-367-8667) M - F 8:30 a.m. - 5 p.m. ET

PRINCIPAL DISPLAY PANEL - 85 g Tube

SINCE 1970

Tom's®

OF MAINE

natural

fluoride

TOOTHPASTE

cavity protection | whitening | fresh breath

fresh mint

NET WT 3 OZ (85 g)

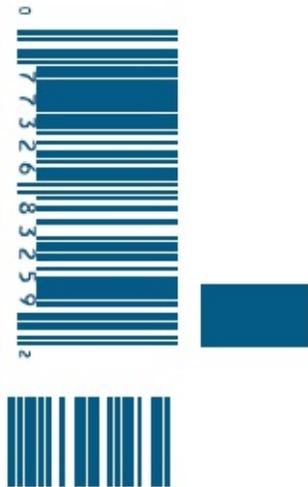
TWIST OFF CAP AND REMOVE FOIL SEAL DO NOT USE IF SEAL IS NOT INTACT P9879803 1081
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fluoride
natural TOOTHPASTE
 cavity protection | whitening | fresh breath
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Drug Facts		Drug Facts (continued)	
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Use helps protect against cavities		children under 2 years	ask a dentist or physician
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		*Peppermint oil and other natural flavor	



**NATURAL FLUORIDE FRESH MINT CAVITY PROTECTION
 WHITENING FRESH BREATH**

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-238
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZXC1474W7) (FLUORIDE ION)		

SODIUM FLUORIDE (UNII: 8Z YQ14/4W/) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.00243 g in 1 g
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Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	

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:51009-238-59	85 g in 1 TUBE; Type 0: Not a Combination Product	09/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	09/01/2012	

Labeler - Tom's of Maine, Inc. (052764354)

Revised: 12/2022

Tom's of Maine, Inc.