

**SENSITIVE FLUORIDE-FREE - WINTERMINT- potassium nitrate 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.

**Tom's™
OF MAINE**

Drug Facts

Active ingredients

Potassium nitrate 5%

Purpose

Tooth desensitizer

Use

builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact

Warnings

When using this product, do not use longer than 4 weeks unless recommended by a dentist or physician.

Stop use and ask a dentist if the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.

Keep out of reach of children. 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 12 years of age and older apply at least a 1-inch strip of the product onto a soft bristle toothbrush. Brush teeth thoroughly at least 1 minute twice a day (morning and evening) or as recommended by a dentist or physician. Make sure to brush all sensitive areas of the teeth.
- children under 12 years of age: consult a dentist or physician

Inactive ingredients

sorbitol, water, hydrated silicas, xylitol, glycerin, organic Aloe barbadensis leaf juice, natural flavors, sodium lauryl sulfate, cocamidopropyl betaine, xanthan gum, titanium dioxide.

Questions?

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

PRINCIPAL DISPLAY PANEL - 113 g Tube Carton

SINCE 1970
Tom's
OF MAINE™

fluoride-free
natural

SENSITIVE

clinically proven ingredient to reduce painful sensitivity
toothpaste for sensitive teeth

wintermint

NET WT 4.0 OZ (113 g)

fluoride-free
SENSITIVE
We do it naturally!
Tom's of Maine uses the same, FDA-allowed, maximum strength ingredient to fight tooth sensitivity as the leading brand. We source naturally occurring nitrate ore for our active ingredient Potassium Nitrate, clinically proven to help reduce and relieve your painful sensitivity caused by exposed dentin on the surface of your teeth. Some consumers prefer a product without fluoride, which is why we are pleased to offer a fluoride-free version of our sensitive toothpaste!

© 2010 Tom's of Maine, Inc., 302 Lafayette Ctr., Kennebunk, ME 04043 Made in U.S.A. © ⓘ

enamel
nerve
exposed dentin

fluoride-free | **natural**
SENSITIVE
clinically proven ingredient to reduce painful sensitivity
toothpaste for sensitive teeth
wintermint
NET WT 4.0 OZ (113 g)

fluoride-free
SENSITIVE
toothpaste for sensitive
wintermint

0 77326 119704 2

Drug Facts	Drug Facts (continued)
Active Ingredients Potassium nitrate 5%	Purpose Tooth desensitizer
Use builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact	Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or dial (412) 390-3381 right away (Poison Control Center).
Warnings When using this product, do not use longer than 4 weeks unless recommended by a dentist or physician. Stop use and ask a dentist if the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.	Directions • adults and children 12 years of age and older apply at least a 1-inch strip of the product onto a soft bristle toothbrush. Brush teeth thoroughly at least 1 minute twice a day (morning and evening) or as recommended by a dentist or physician. Make sure to brush all sensitive areas of the teeth. • children under 12 years of age, consult a dentist or physician.
	Inactive Ingredients sorbitol, water, hydrated silica, xylitol, glycerin, organic Aloe barbadensis leaf juice, natural flavors, sodium lauryl sulfate, cocamidopropyl betaine, xanthan gum, titanium dioxide.
	Questions? 1-800-FOR-TOMS (1-800-367-8667) M - F 8:30 a.m. - 5:30 p.m. ET

#P9859103

What makes a product good? At Tom's, it includes how we make it.

- No animal testing or animal ingredients.** (PETA logo)
- No artificial colors, flavors, fragrance, or preservatives.**
- We share every ingredient, its purpose, and its source at www.tomsforme.com.** (I.P.S. logo)
- We strive to maximize recycled content and recyclability of our packaging.** (Recycling logo)
- Sustainable practices are a priority in every aspect of our business.** (Footprint logo)
- 5% (12 days) of employee time to volunteering. 10% of profits to human and environmental goodness.** (Heart logo)

Tom's of Maine™ Goodness Day
Company Volunteer Day with The Nature Conservancy

Visit www.tomsforme.com or find us on: [Facebook](#) [Twitter](#) [YouTube](#)

0 77326 119704 2

SENSITIVE FLUORIDE-FREE - WINTERMINT

potassium nitrate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 09-197
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Potassium Nitrate (UNII: RU45X2JN0Z) (Nitrate Ion - UNII:T93E9Y2844)	Potassium Nitrate	0.05 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
sorbitol (UNII: 506T60A25R)	
hydrated silica (UNII: Y607T4G8P9)	
xylitol (UNII: VCQ006KQ1E)	
glycerin (UNII: PDC6A3C00X)	
water (UNII: 059QF0K00R)	
cocamidopropyl betaine (UNII: 5OCF3O11KX)	
sodium lauryl sulfate (UNII: 368GB5141J)	
xanthan gum (UNII: TTV12P4NEE)	
peppermint oil (UNII: AV092KU4JH)	
titanium dioxide (UNII: 15FIX9V2JP)	
spearmint oil (UNII: C3M81465G5)	
menthol, unspecified form (UNII: L7T10EIP3A)	
glycyrrhizin (UNII: 6FO62043WK)	
star anise oil (UNII: 6RXP35EIRE)	
methyl salicylate (UNII: LAV5U5022Y)	
aloe vera leaf (UNII: ZY81Z83H0X)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	WINTERGREEN (Wintermint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51009-197-04	1 in 1 CARTON	09/01/2009	
1		113 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 not final	part356	09/01/2009	

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

Name	Address	ID/FEI	Business Operations
Tom's of Maine, Inc.		829517189	MANUFACTURE(51009-197)

Revised: 9/2019

Tom's of Maine, Inc.