# TOMS WHOLE CARE WINTERMINT FIGHTS CAVITIES / WHITENING / FRESH BREATH / HELPS FIGHT TARTAR / NO ARTIFICIAL DYES OR SWEETENERS- sodium monofluorophosphate 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.

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 $Toms_{\, \mathbb{R}}$  Whole  $Care^{\, \mathbb{R}}$  Wintermint Toothpaste fights cavities / whitening / fresh breath / helps fight tartar / no artificial dyes or sweeteners  $Drug\ Facts$ 

#### **Active ingredient**

Sodium monofluorophosphate 0.76% (0.14% 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**

water, hydrated silica, sorbitol, xylitol, glycerin, natural flavor<sup>1</sup>, sodium lauryl sulfate, zinc citrate, xanthan gum, titanium dioxide, carrageenan.

#### Questions?

1-800-FOR-TOMS (1-800-367-8667)

<sup>1</sup> wintergreen oil and other natural flavor

### PRINCIPAL DISPLAY PANEL - 133 g Tube Carton

SINCE 1970 Tom's® OF MAINE

with fluoride | natural

WHOLE CARE®

### fluoride toothpaste

fights cavities whitening fresh breath helps fight tartar no artificial dyes or sweeteners

#### wintermint

NET WT 4.7 OZ (133 g)



with fluoride natura **IOHW** 

fluoride toothpaste

fights cavities whitening

fresh breath no artificial dyes or sweeteners helps fight tartar



WT 4.7 OZ (133 g) F

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



No animal testing or animal Ingredients.



We share every ingredient, Its purpose, and Its source at www.tomsofmaine.com.



Sustainable practices are a priority in every aspect of our business.



No artificial colors, flavors, fragrance, or preservatives.



We strive to maximize recycled content and recyclability of our packaging.



5% (12 days) of employee time to volunteering. 10% of profits to human and environmental goodness.



Employee Volunteer Day Mt. Agamenticus - York, Maine

We believe what's inside matters? Our Stewardship Model guides every decision we make, ensuring that our ingredients, processing, and packaging meet our rigorous standards for being natural, sustainable, and responsible. To learn more about our Stewardship Model and what "natural" means at Tom's of Maine, visit www.tomsofmaine.com

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#### with fluoride

natural

#### fluoride toothpaste

fights cavities | whitening | fresh breath | helps fight tartar no artificial dyes or sweeteners

wintermint

NET WT 4.7 OZ (133 g)



#### **Drug Facts**

Active ingredient
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Use helps protect against cavities

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Directions

#### Drug Facts (continued)

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Inactive ingredients water, hydrated silica, sorbitol, xylitol, glycerin, natural flavor\*, sodium lauryl sulfate, zinc citrate, xanthan gum, titanium dioxide, carrageenan.

Questions? 1-800-FOR-TOMS (1-800-367-8667)

#### Goodness = Less In Landfills

Recycle Tom's of Maine' and other packaging through the TerraCycle' collection program and earn rewards for your favorite nonprofit or school. Visit www.tomsofmaine.com/terracycle to large how

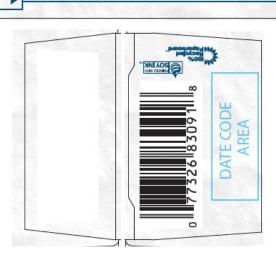
to learn how.

Helps prevent tartar buildup with regular brushing.

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\*wintergreen oil and other natural flavor

(M) **BPA-Free Tube** 





## TOMS WHOLE CARE WINTERMINT FIGHTS CAVITIES / WHITENING / FRESH BREATH / HELPS FIGHT TARTAR / NO ARTIFICIAL DYES OR SWEETENERS

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-212
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Route of Administration DENTAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	1.4 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
SORBITOL (UNII: 506T60A25R)		

XYLITOL (UNII: VCQ006KQ1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
SODIUM LAURYL SULFATE (UNII: 368 GB5141J)	
ZINC CITRATE (UNII: K72I3DEX9B)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
CARRAGEENAN (UNII: 5C69 YCD2YJ)	

Product Characteristics			
Color	WHITE (Off White)	Score	
Shape		Size	
Flavor	WINTERGREEN (Wintermint)	Imprint Code	
Contains			

F	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:51009-212-47	1 in 1 CARTON	03/01/2015	
1		133 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	0 3/0 1/20 15	

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Tom's of Maine, Inc.		829517189	MANUFACTURE(51009-212)	

Revised: 2/2015 Tom's of Maine, Inc.