

**SIMPLY WHITE CLEAN MINT- 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.

**Tom's
OF MAINE
SIMPLY WHITE®
fluoride toothpaste
clean mint**

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

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

1 peppermint oil and other natural flavor

Questions?

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

PRINCIPAL DISPLAY PANEL - 113 g Tube Carton

THE ORIGINAL
Tom's
OF MAINE

ADA
Accepted
American
Dental
Association ®

NATURAL • WITH FLUORIDE

SIMPLY
WHITE®

anticavity toothpaste

CLEAN MINT

4.0 OZ (113 g)

CLINICALLY PROVEN
WHITENING

REMINERALIZES ENAMEL

PREVENTS CAVITIES

NO
ANIMAL TESTING,
ARTIFICIAL FLAVORS,
SWEETENERS OR DYES

THE ORIGINAL Tom's OF MAINE
Simply White®
 anticavity toothpaste

ADA Accepted American Dental Association
 VEGAN
 NOT TESTED ON ANIMALS
 10% PROFITS TO CHARITY
 EST 1970

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We've combined scientific know-how and naturally sourced and derived ingredients to make products that are good for you since 1970. Beyond making effective products, Tom and Kate created Tom's of Maine to be a force for good and that still drives us today! We've got big goals to help combat climate change and social inequities, which is why we donate to non-profit organizations that focus on climate change, health and well-being and disaster relief.

To learn more about our mission, rigorous ingredient and packaging standards, and what natural means at Tom's, go to www.tomsforme.com. You will find every ingredient's purpose and source there too.

★ THOUGHTFULLY BLENDED & PACKAGED IN THE USA WITH US & GLOBALLY SOURCED INGREDIENTS ★

© TOM'S OF MAINE INC., KENNEBUNK ME 04043 U.S.A.

THIS PRODUCT IS:

- GLUTEN FREE
- VEGAN
- HALAL
- KOSHER

DO GOOD EVERYDAY WITH TOM'S
 Certified B Corporation
 ANIMAL TEST-FREE PETA
 CERTIFIED GOOD GUYS, PARTNER OF TOM'S OF MAINE
 10% PROFITS TO CHARITY

THE FIRST OF ITS KIND RECYCLABLE TUBE

Your community may not yet accept tubes for recycling. Check locally. Learn more at tomsforme.com/recyclable-tube

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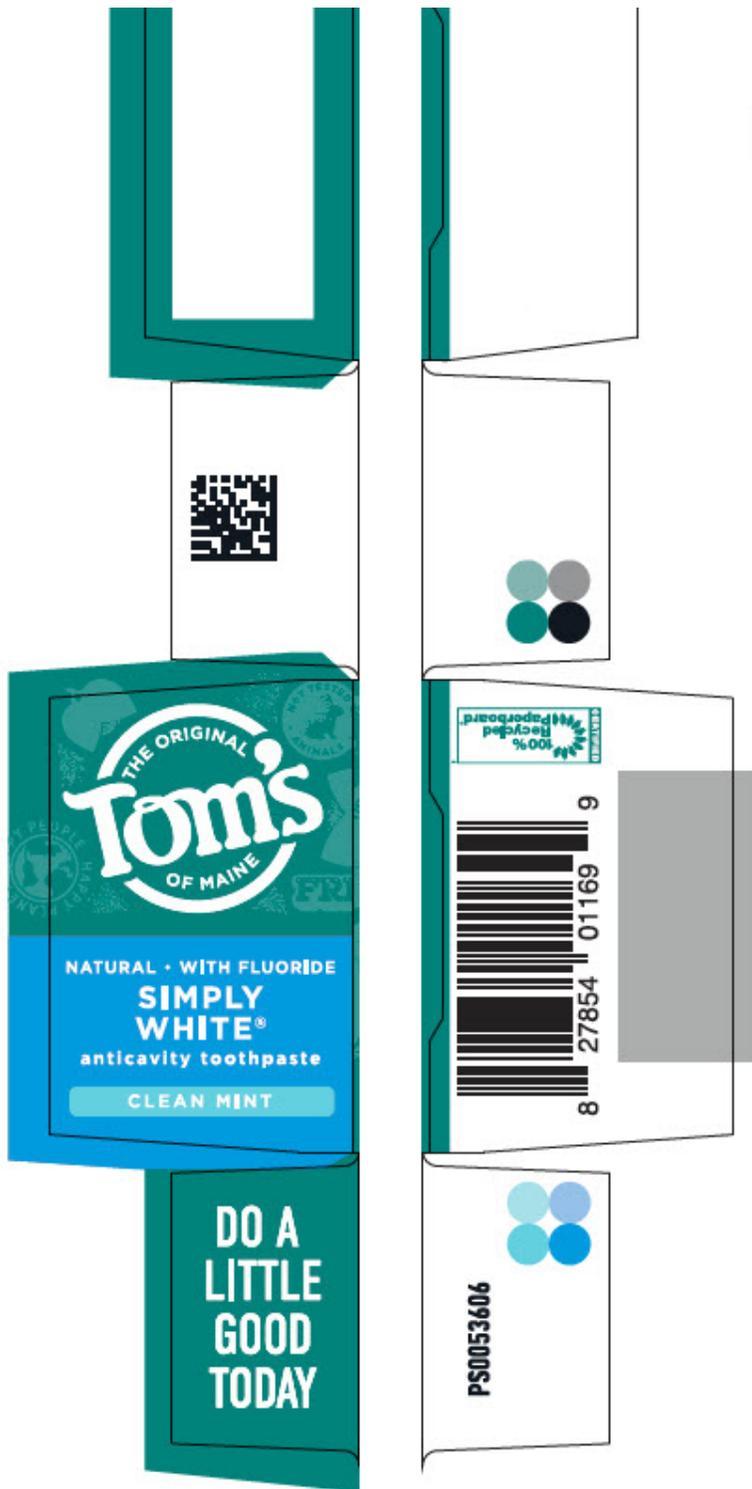
Drug Facts		Drug Facts (continued)	
Active ingredient	Purpose	adults and children 2 years of age and older	brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician
Sodium fluoride 0.24% (0.15% w/v fluoride ion)	Anticavity	children 2 to 6 years	use only a pea-sized amount and supervise child's brushing and rinsing (to minimize swallowing)
Use helps protect against cavities		children under 2 years	ask a dentist or physician
Warnings		Inactive ingredients water, sorbitol, hydrated silica, xylitol, glycerin, sodium lauryl sulfate, natural flavor*, xanthan gum, sodium hydroxide, carrageenan, titanium dioxide.	
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).		Questions? 1-800-FOR-TOMS (1-800-367-8667)	
Directions			

Formula contains naturally derived fluoride to fight cavities and strengthen enamel as well as naturally derived silica to whiten teeth.

- Helps prevent cavities
- Helps remove tooth surface stain

*peppermint oil and other natural flavor





SIMPLY WHITE CLEAN MINT

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-248
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.00243 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	MINT (Clean Mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51009-248-47	1 in 1 CARTON	08/29/2011	
1		133 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51009-248-40	1 in 1 CARTON	09/30/2023	
2		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 FINAL	part355	08/29/2011	

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

