

WHOLE CARE ORANGE MANGO- sodium fluoride paste, dentifrice
WHOLE CARE SPEARMINT- sodium fluoride paste, dentifrice
WHOLE CARE PEPPERMINT- 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
WHOLE CARE
fluoride toothpaste gel**

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

sorbitol, hydrated silica, water, glycerin, *Citrus aurantium dulcis* (orange) peel oil and other natural flavors, xylitol, sodium lauryl sulfate, zinc citrate, xanthan gum.

Questions?

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

PRINCIPAL DISPLAY PANEL - 133 g Carton

Since 1970

Tom's

OF MAINE™

with fluoride | natural

WHOLE CARE®

fighting cavities | whitening | fresh breath | helps fight tartar

fluoride toothpaste

orange mango gel

NET WT 4.7 OZ (133 g)



natural
with fluoride

WHOLE CARE[®]

fights cavities
 whitening
 fresh breath
 helps fight tartar

fluoride toothpaste
orange mango gel



NET WT 4.7 OZ (133 g)

What makes a product 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.



Tom's of Maine™ Goodness Day

You asked – we listened!
This tube is easier to use than our previous tube. Learn more about how this tube reinforces our commitment to environmental stewardship at: www.tomsofmaine.com

Find us on:



with fluoride | natural

WHOLE CARE[®]

fights cavities | whitening | fresh breath | helps fight tartar

fluoride toothpaste
orange mango gel



NET WT 4.7 OZ (133 g)

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 ▶

Drug Facts (continued)

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 sorbitol, hydrated silica, water, glycerin, Citrus aurantium dulcis (orange) peel oil and other natural flavors, xylitol, sodium lauryl sulfate, zinc citrate, xanthan gum.

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

Along with clinically-proven cavity protection from fluoride, this toothpaste whitens with naturally sourced silicas. This product also helps to freshen breath and prevent plaque and tartar buildup with regular brushing.

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

PRINCIPAL DISPLAY PANEL - 133 g Carton

Since 1970
Tom's
OF MAINE[™]
with fluoride | natural
WHOLE CARE[®]
 fights cavities | whitening | fresh breath | helps fight tartar
fluoride toothpaste
peppermint gel
NET WT 4.7 OZ (133 g)



natural
with fluoride

WHOLE CARE

fights cavities
 whitening
 fresh breath
 helps fight tartar

fluoride toothpaste
 peppermint gel



NET WT 4.7 OZ (133 g)

What makes a product 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.



Tom's of Maine™ Goodness Day

You asked – we listened!

This tube is easier to use than our previous tube. Learn more about how this tube reinforces our commitment to environmental stewardship at: www.tomsofmaine.com

Find us on:



with fluoride | natural

WHOLE CARE

fights cavities | whitening | fresh breath | helps fight tartar

fluoride toothpaste
 peppermint gel



NET WT 4.7 OZ (133 g)

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

Drug Facts (continued)

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 sorbitol, hydrated silica, water, glycerin, xylitol, *Mentha piperita* (peppermint) oil and other natural flavors, sodium lauryl sulfate, zinc citrate, xanthan gum.

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

Along with clinically-proven cavity protection from fluoride, this toothpaste whitens with naturally sourced silicas. This product also helps to freshen breath and prevent plaque and tartar buildup with regular brushing.

© 2010 Tom's of Maine, Inc.
302 Lafayette Ctr.
Kennebunk, ME 04043

Made in U.S.A.

PRINCIPAL DISPLAY PANEL - 133 g Carton

Since 1970

Tom's
OF MAINE™

with fluoride | natural

WHOLE CARE®

fights cavities | whitening | fresh breath | helps fight tartar

fluoride toothpaste

spearmint gel

NET WT 4.7 OZ (133 g)



natural
with fluoride

WHOLE CARE[®]

fights cavities
whitening
fresh breath
helps fight tartar

fluoride toothpaste
spearmint gel



NET WT 4.7 OZ (133 g)

What makes a product 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.



You asked – we listened!
This tube is easier to use than our previous tube. Learn more about how this tube reinforces our commitment to environmental stewardship at: www.tomsofmaine.com

Find us on:






with fluoride | natural

WHOLE CARE[®]

fights cavities | whitening | fresh breath | helps fight tartar

fluoride toothpaste
spearmint gel



NET WT 4.7 OZ (133 g)

Drug Facts		Drug Facts (continued)	
Active ingredient Sodium fluoride 0.24% (0.15% w/v fluoride ion)	Purpose Anticavity	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
Use helps protect against cavities		children 2 to 6 years	use only a pea-sized amount and supervise child's brushing and rinsing (to minimize swallowing)
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).		children under 2 years	ask a dentist or physician
Directions		Inactive ingredients sorbitol, hydrated silica, water, glycerin, xylitol, Mentha viridis (spearmint) leaf oil and other natural flavors, sodium lauryl sulfate, zinc citrate, xanthan gum.	
		Questions? 1-800-FOR-TOMS (1-800-367-8667) M - F 8:30 a.m. - 5:30 p.m. ET	

Along with clinically-proven cavity protection from fluoride, this toothpaste whitens with naturally sourced silicas. This product also helps to freshen breath and prevent plaque and tartar buildup with regular brushing.

© 2010 Tom's of Maine, Inc.
302 Lafayette Ctr.
Kennebunk, ME 04043

Made in U.S.A. 

WHOLE CARE ORANGE MANGO

sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-119
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)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
Xylitol (UNII: VCQ006KQ1E)	
Sodium lauryl sulfate (UNII: 368GB5141J)	
Zinc citrate (UNII: K72I3DEX9B)	
Xanthan gum (UNII: TTV12P4NEE)	
Mango (UNII: I629I3NR86)	
Orange Oil (UNII: AKN3KSD11B)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	ORANGE, MANGO (Fruity)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51009-119-47	1 in 1 CARTON	02/14/2011	
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	02/14/2011	

WHOLE CARE SPEARMINT

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-153
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)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0K00R)	
Xylitol (UNII: VCQ006KQ1E)	
Sodium lauryl sulfate (UNII: 368GB5141J)	
Zinc citrate (UNII: K72I3DEX9B)	
Xanthan gum (UNII: TTV12P4NEE)	
Spearmint Oil (UNII: C3M81465G5)	
Peppermint oil (UNII: AV092KU4JH)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	SPEARMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51009-153-47	1 in 1 CARTON	02/14/2011	
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	02/14/2011	

WHOLE CARE PEPPERMINT

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-158
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)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
Xylitol (UNII: VCQ006KQ1E)	
Sodium lauryl sulfate (UNII: 368GB5141J)	
Zinc citrate (UNII: K72I3DEX9B)	
Xanthan gum (UNII: TTV12P4NEE)	
Peppermint oil (UNII: AV092KU4JH)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51009-158-47	1 in 1 CARTON	02/14/2011	
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	02/14/2011	

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

Establishment

Name	Address	ID/FEI	Business Operations
Tom's of Maine, Inc.		829517189	MANUFACTURE(51009-119, 51009-153, 51009-158)

Revised: 9/2019

Tom's of Maine, Inc.