CAVITY PROTECTION PEPPERMINT WITH BAKING SODA- sodium monofluorophosphate paste, dentifrice CAVITY PROTECTION SPEARMINT- 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.

Tom's
OF MAINE
CAVITY PROTECTION
fluoride toothpaste

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.76% (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

vears 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 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

calcium carbonate, water, glycerin, sodium bicarbonate, *Chondrus crispus* (carrageenan), *Mentha piperita* (peppermint) oil, xylitol, sodium lauryl sulfate.

Questions?

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

PRINCIPAL DISPLAY PANEL - 155.9 g Carton

SINCE 1970 Tom's OF MAINETM

baking soda I natural

CAVITY PROTECTION

fights cavities [] fresh breath

fluoride toothpaste

peppermint

ADA

Accepted

American

Dental

Association ®

NET WT 5.5 OZ (155.9 g)





baking soda | natural

CAVITY PROTECTION

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

fights cavities | fresh breath fluoride toothpaste

peppermint

NET WT 5.5 OZ (155.9 g)



Drug Facts	Drug Facts (continued)		
Active Ingredient Purpose Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion) 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	children under 2 years	ask a dentist or physician	
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).	Inactive ingredients calcium carbonate, water, glycerin, sodium bicarbonate, Chondrus crispus (carrageenan), Mentha piperita (peppermint) oil, xylitol, sodium laurul sulfate.		
Directions >	Questions? 1-800-FOR-T	OMS (1-800-367-8667) M - F 8:30 a.m 5:30 p.m. ET	

The ADA Council on Scientific Affairs' Acceptance of Tom's of Maine Natural Cavity Protection Fluoride Toothpaste is based on its finding that the product is effective in helping to prevent and reduce tooth decay, when used as directed."

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Made in U.S.A. 🔞 🛈

PRINCIPAL DISPLAY PANEL - 155.9 g Carton

SINCE 1970 Tom's OF MAINETM

natural

CAVITY PROTECTION

fights cavities [] fresh breath

fluoride toothpaste

spearmint

ADA Accepted

American Dental

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NET WT 5.5 OZ (155.9 g)



fresh breath fights cavities luoride toothpaste



5.5 OZ (155.9 M ы

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.





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:







natural

CAVITY PROTECTION





fights cavities | fresh breath fluoride toothpaste



NET WT 5.5 OZ (155.9 g)



Active ingredient regient Purpose prophosphate 0.76% (0.15% w/v fluoride ion) 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)

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

Inactive Ingredients calcium carbonate, water, glycerin, xylitol, sodium lauvyl sulfate, Mentha vividis (spearmint) leaf oil and other natural flavors, Chondrus crispus (carrageenan).

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

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CAVITY PROTECTION PEPPERMINT WITH BAKING SODA

sodium monofluorophosphate paste, dentifrice

Product	Information
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:51009-120

Route of Administration DENTAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Sodium Monofluorophosphate (UNII: C810JCZ56Q) (Fluoride ion UNII:Q80VPU408O) Sodium Monofluorophosphate in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
Calcium carbonate (UNII: H0G9379FGK)			
Glycerin (UNII: PDC6A3C0OX)			
Water (UNII: 059QF0KO0R)			
Sodium Bicarbonate (UNII: 8MDF5V39QO)			
Carrageenan (UNII: 5C69 YCD2YJ)			
Xylitol (UNII: VCQ006KQ1E)			
Sodium Lauryl Sulfate (UNII: 368GB5141J)			
Peppermint oil (UNII: AV092KU4JH)			

Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor	PEPPERMINT	Imprint Code		
Contains				

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:51009-120-55	1 in 1 CARTON			
1		155.9 g in 1 TUBE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	02/14/2011	

CAVITY PROTECTION SPEARMINT

sodium monofluorophosphate paste, dentifrice

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-116	
Route of Administration	DENTAL			

Active	Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength	
	Monofluorophosphate (UNII: C810JCZ56Q) (Fluoride ion - 0VPU408O)	So dium Mo no fluo ro pho sphate	0.0076 g in 1 g	

Inactive Ingredients			
Ingredient Name	Strength		
Calcium carbonate (UNII: H0G9379FGK)			
Glycerin (UNII: PDC6A3C0OX)			
Water (UNII: 059QF0KO0R)			
Xylitol (UNII: VCQ006KQ1E)			
Carrageenan (UNII: 5C69 YCD2YJ)			
Sodium Lauryl Sulfate (UNII: 368GB5141J)			
Spearmint Oil (UNII: C3M8 146 5G5)			
Peppermint oil (UNII: AV092KU4JH)			

Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor	SPEARMINT	Imprint Code		
Contains				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:51009-116-55	1 in 1 CARTON			
1	155.9 g in 1 TUBE			

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.		052764354	MANUFACTURE		

Revised: 5/2011 Tom's of Maine, Inc.