

MAXIMUM STRENGTH SENSITIVE TRUE MINT- sodium fluoride and 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

<i>Active ingredients</i>	<i>Purpose</i>
Potassium nitrate 5%	Tooth desensitizer
Sodium fluoride 0.24% (0.15 w/v fluoride ion)	Anticavity

Uses

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

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, hydrated silica, xylitol, water, glycerin, organic *Aloe barbadensis* leaf juice, *Mentha piperita* (peppermint) oil and other natural flavors, 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

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

PRINCIPAL DISPLAY PANEL - 113 g Box

SINCE 1970

**Tom's
OF MAINE™**

maximum strength* | natural

SENSITIVE

clinically proven to reduce painful sensitivity

**toothpaste for sensitive teeth
and cavity prevention with fluoride**

true mint

NET WT 4.0 OZ (113 g)



natural
maximum strength*

SENSITIVE

clinically proven to
reduce painful sensitivity

toothpaste for sensitive teeth
and cavity prevention with fluoride

true mint



NET WT 4.0 OZ (113 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:



maximum strength* | natural

SENSITIVE

clinically proven to reduce painful sensitivity

toothpaste for sensitive teeth
and cavity prevention with fluoride

true mint



NET WT 4.0 OZ (113 g)

Drug Facts

Active ingredients

Potassium nitrate 5% Tooth desensitizer
Sodium fluoride 0.24% (0.15 w/v fluoride ion) Anticavity

Purpose

..... Tooth desensitizer
..... Anticavity

Uses • builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact • helps protect against cavities

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.

Drug Facts (continued)

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, hydrated silica, xylitol, water, glycerin, organic Aloe barbadensis leaf juice, Mentha piperita (peppermint) oil and other natural flavors, cocamidopropyl betaine, xanthan gum, titanium dioxide.

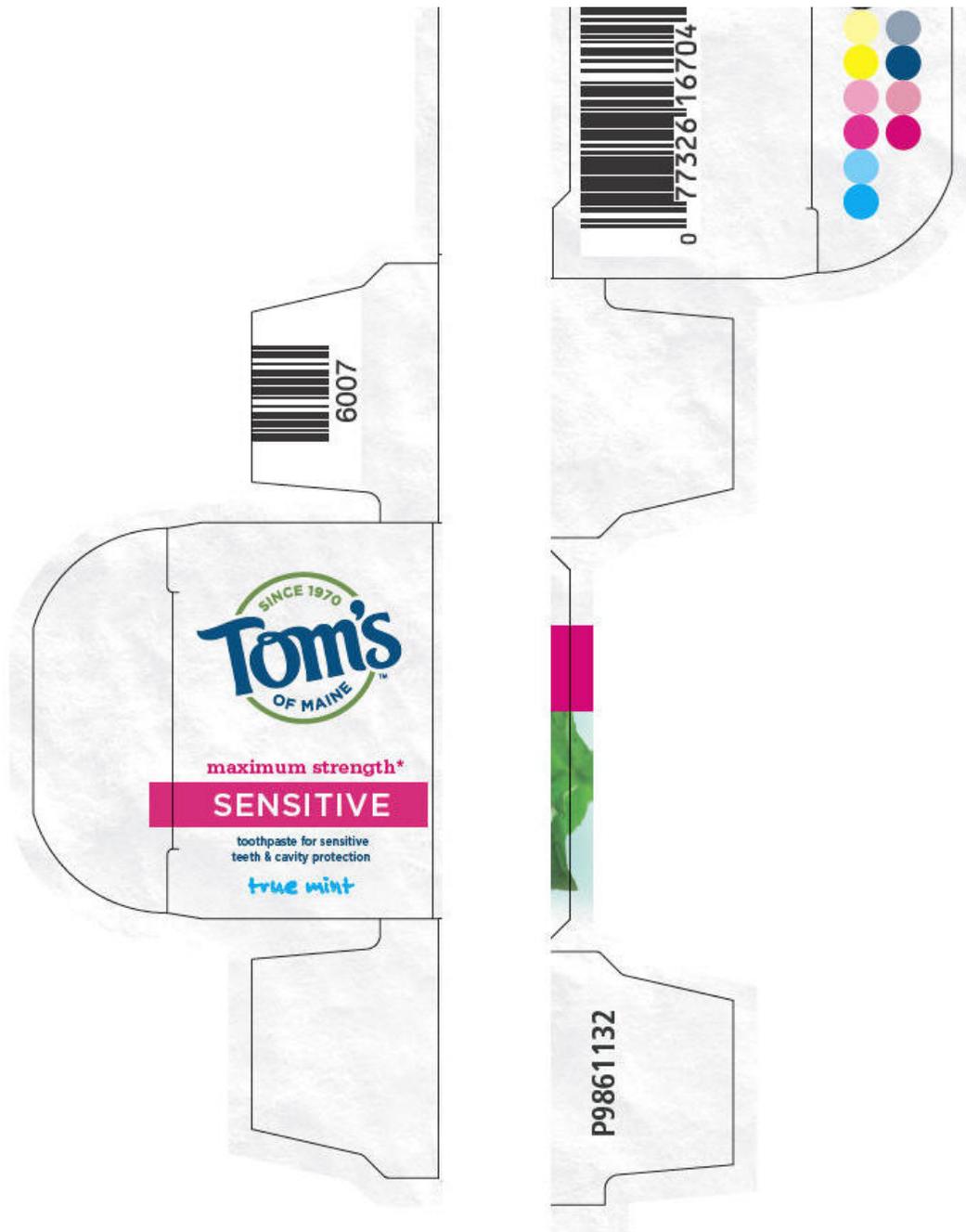
Questions? 1-800-FOR-TOMS (1-800-367-8667) M - F 8:30 a.m. - 5:30 p.m. ET

*Maximum FDA allowed antisensitivity active ingredient

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

Made in U.S.A.





MAXIMUM STRENGTH SENSITIVE TRUE MINT

sodium fluoride and potassium nitrate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51009-167
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
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: Y6O7T4G8P9)	
xylitol (UNII: VCQ006KQ1E)	
glycerin (UNII: PDC6A3C0OX)	
water (UNII: 059QF0K00R)	
aloe vera leaf (UNII: ZY81Z83H0X)	
cocamidopropyl betaine (UNII: 5OCF3O11KX)	
xanthan gum (UNII: TTV12P4NEE)	
peppermint oil (UNII: AV092KU4JH)	
titanium dioxide (UNII: 15FIX9V2JP)	
spearmint oil (UNII: C3M81465G5)	
menthol, unspecified form (UNII: L7T10EIP3A)	
glycyrrhizin (UNII: 6FO62043WK)	
Anise (UNII: 21C2F5E8RE)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	SPEARMINT (True Mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51009-167-04	1 in 1 BOX	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(51009-167)