

**SMARTMOUTH ADVANCE CLINICAL FORMULA- sodium monofluorophosphate paste, dentifrice**

**Triumph Pharmaceuticals 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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**Smart  
Mouth™  
ADVANCED  
CLINICAL FORMULA™  
TOOTHPASTE**

***Drug Facts***

**Active Ingredient**

Sodium monofluorophosphate (0.81%) (0.10% w/v of fluoride ion)

**Purpose**

Anticavity

**Use**

- Aids in the prevention of dental 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 contact a Poison Control Center right away.

**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 doctor.
- Children 2 to 6 years of age: Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.
- Children under 2 years of age: Consult a dentist or doctor.

**Inactive Ingredients**

Sorbitol, Hydrated Silica, Glycerin, Water, Sodium Lauryl Sulfate, Flavor, Titanium Dioxide, Xanthan Gum, Sodium Benzoate, Benzoic Acid, Sodium Saccharin, Zinc Chloride, D&C Yellow #10 and FD&C Blue #1

**Questions or comments**

**1-800-492-7040**

SmartMouth™ is a trademark of  
and distributed by:

**Triumph**

**Pharmaceuticals Inc.**

St. Louis, Missouri 63132

Made in USA ©2011

**PRINCIPAL DISPLAY PANEL - 170 g Tube Label**

smart

mouth™

PREMIUM

TOOTHPASTE

Clinically Developed By Dentists

Zn<sup>+2</sup>

Protect

Repair

Clean

MILD FLAVOR / NO AFTERTASTE

ANTI-CAVITY WITH FLUORIDE

REMOVES DENTAL PLAQUE

REMINERALIZES ENAMEL

SENSITIVE WHITENING

GUARANTEED

MILD MINT • NET WT. 6 OZ (170g)



# PREMIUM TOOTHPASTE

Clinically Developed By Dentists



MILD FLAVOR / NO AFTERTASTE

ANTI-CAVITY WITH FLUORIDE

REMOVES DENTAL PLAQUE

REMINERALIZES ENAMEL

SENSITIVE WHITENING

**GUARANTEED**

MILD MINT • NET WT. 6 OZ (170g)



SmartMouth™ Premium Toothpaste uses Smart-Zinc™ technology in conjunction with other premium features to provide superior oral health protection all with a mild mint flavor and no aftertaste.

For best results, use with any SmartMouth™ Oral Rinse.

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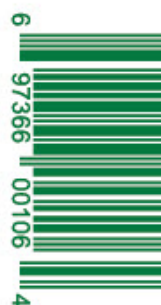
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**Questions or comments:** 1-800-492-7040

## SATISFACTION GUARANTEE:

If you are not completely satisfied with SmartMouth™ Toothpaste after using twice daily for a minimum period of 2 weeks, please have your sales receipt on hand & call 1-800-492-7040. Limit one refund per household.



Also, try our entire family of SmartMouth™ products.  
View them at [www.SmartMouth.com](http://www.SmartMouth.com)

**smartmouth™**  
ORAL HEALTH LABORATORIES

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Triumph Pharmaceuticals Inc., St. Louis, Missouri 63141  
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sodium monofluorophosphate paste, dentifrice				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76357-106	
Route of Administration	DENTAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (Fluoride Ion - UNII:Q80VPU408O)		Fluoride Ion	1 mg in 1 g	
Inactive Ingredients				
Ingredient Name		Strength		
Sorbitol (UNII: 506T60A25R)				
Hydrated Silica (UNII: Y6O7T4G8P9)				
Glycerin (UNII: PDC6A3C0OX)				
Water (UNII: 059QF0KO0R)				
Sodium Lauryl Sulfate (UNII: 368GB5141J)				
Titanium Dioxide (UNII: 15FIX9V2JP)				
Xanthan Gum (UNII: TTV12P4NEE)				
Sodium Benzoate (UNII: OJ245FE5EU)				
Benzoic Acid (UNII: 8SKN0B0MIM)				
Saccharin Sodium (UNII: SB8ZUX40TY)				
Zinc Chloride (UNII: 86Q357L16B)				
D&C Yellow No. 10 (UNII: 35SW5USQ3G)				
FD&C Blue No. 1 (UNII: H3R47K3TBD)				
Product Characteristics				
Color	GREEN	Score		
Shape		Size		
Flavor	MINT (mint vanilla)	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76357-106-04	170 g in 1 TUBE; Type 0: Not a Combination Product	06/17/2011	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL		part355	06/17/2011	

