

**SMARTMOUTH PREMIUM ACTION SMARTMOUTH ADVANCED CLINICAL FORMULA (ACF)- 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.

**SmartMouth™ Premium Action Toothpaste
SmartMouth™ Toothpaste Advanced Clinical Formula (ACF)**

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 63114**

PRINCIPAL DISPLAY PANEL - 96.4 g Tube Label

smart
mouth™

PREMIUM
TOOTHPASTE

Clinically Developed By Dentists

Zn⁺²
Protect
Repair
Clean

MILD FLAVOR / NO AFTERTASTE

ANTI-CAVITY WITH FLUORIDE

REMOVES DENTAL PLAQUE

REMINERALIZES ENAMEL

SENSITIVE WHITENING

GUARANTEED

MILD MINT • NET WT. 3.4 OZ (96.4g)



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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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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



***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.



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 Also, try our entire family of SmartMouth™ products. View them at www.SmartMouth.com

SMARTMOUTH PREMIUM ACTION SMARTMOUTH ADVANCED CLINICAL FORMULA (ACF)

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76357-175
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (Fluoride Ion -	Fluoride Ion	10.21 g

UNII:Q80VPU408O)

Fluoride Ion

in 96.4 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)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	MINT, VANILLA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76357-175-00	96.4 g in 1 TUBE; Type 0: Not a Combination Product	02/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/01/2018	

Labeler - Triumph Pharmaceuticals Inc. (017853461)

Revised: 2/2023

Triumph Pharmaceuticals Inc.