

**SMARTMOUTH SMARTMOUTH GUM HEALTH ZINC ACTIVATED FORMULA-
cetylpyridinium chloride
Triumph Pharmaceuticals, Inc.**

**SmartMouth™ Mouthwash
SmartMouth™ Gum Health Zinc Activated Formula**

Drug Facts

Active Ingredient

Cetylpyridinium Chloride 0.05% (when mixed as directed)

Purpose

Anti-gingivitis/Anti-plaque

Uses

Helps prevent and reduce plaque and gingivitis. Helps control plaque bacteria that contribute to the development of gingivitis and bleeding gums.

Warnings

Ask a dentist if symptoms persist or condition worsens after regular use.

Keep out of reach of children under 6 years of age. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **Use after your normal brushing and flossing routine**
- **Adults and children 12 years of age & older:** vigorously swish 20 mL of rinse (pour to indicator line on cap) twice a day for 30 seconds and then spit out. Do not swallow.
- **Children 6 years to under 12 years of age:** supervise use.
- **Children under 6 years of age:** do not use unless directed by a healthcare professional.

Inactive Ingredients

Solution 1: Purified Water, Sodium Benzoate, Sodium Chlorite, and Benzoic Acid. Solution 2: Purified Water, Glycerin, Poloxamer 407, Propylene Glycol, Aloe Vera, Poloxamer 124, Zinc Chloride, Flavor, Sodium Benzoate, Benzoic Acid, Sodium Saccharin, Sodium Chloride, Benzyl Alcohol, D&C Yellow No. 10, FD&C Blue No. 1

Questions?

1-800-492-7040

DISTRIBUTED BY:
TRIUMPH PHARMACEUTICALS INC.
ST. LOUIS, MISSOURI 63141

PRINCIPAL DISPLAY PANEL - Kit Label

MIXES TO ACTIVATE
2 Powerful Solutions

smart
mouth™

Gum Health
Zinc Activated Breath Rinse™

24
HOUR

BAD BREATH
PREVENTION
WITH A MORNING & EVENING RINSE

Advanced Germ Killing⁺
BLEEDING GUMS PROTECTION
SOOTHES WITH NATURAL ALOE

MILD MINT • 16 FL. OZ. (473 mL) • ALCOHOL FREE

TO OPEN
Tear Down
Along
Perforated
Lines



MIXES TO ACTIVATE
2 Powerful Solutions



NOT FOR TRAVEL AFTER OPENING
Find Travel Packs @SmartMouth.com

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Questions? 1-800-492-7040 Use Immediately After Pouring To Ensure Dual Formula Activation.
*Advanced germ killing compared to SmartMouth™ Original Breath Rinse.

PLEASE NOTE: SmartMouth™ is designed to be poured in the forward direction only. To avoid leakage, keep bottle upright and do not squeeze. If spilled on fabric, wash out immediately. Do not use this product if the tamper-evident foil seal is missing or broken. Use within 6 months after opening.

SATISFACTION GUARANTEE: For complete guarantee terms, visit <https://smartmouth.com/satisfaction-guarantee/>

STEP 1

Lift cup and spout to discard green spacer and seal.



STEP 2

Replace cup and spout and push down with palm to secure



Spout Should Face Front of Bottle

STEP 3

Remove cup and pour to line



STEP 4

Rinse, gargle & spit out



Gum Health
Zinc Activated Breath Rinse™

WHY 2 SEPARATE SOLUTIONS?

The power of SmartMouth™ is in the ACTIVATION. Pour the two solutions together to activate the Smart-Zinc™, which eliminates and prevents bad breath for at least 12 hours with each rinse.

- ✓ Dentist Recommended
- ✓ Safe For People with Diabetes



BAD BREATH PREVENTION
WITH A MORNING & EVENING RINSE

Advanced Germ Killing*

BLEEDING GUMS PROTECTION
SOOTHES WITH NATURAL ALOE

QUESTIONS OR COMMENTS?
CALL 1-800-492-7040
WWW.SMARTMOUTH.COM
PATENT SMARTMOUTH.COM/PATENTS

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TRIUMPH PHARMACEUTICALS INC.
ST. LOUIS, MISSOURI 63141
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SMARTMOUTH™
ORAL HEALTH LABORATORIES



MILD MINT • 16 FL. OZ. (473 mL) • ALCOHOL FREE

SMARTMOUTH SMARTMOUTH GUM HEALTH ZINC ACTIVATED FORMULA

cetylpyridinium chloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76357-509
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76357-509-01	1 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2024	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	237 mL
Part 2	1 BOTTLE	237 mL

Part 1 of 2

SMARTMOUTH GUM HEALTH SOLUTION 1

mouthwashes and breath fresheners (liquids and sprays) [oral products] liquid

Product Information

Route of Administration DENTAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	Water (UNII: 059QF0KO0R)	
INGR	Sodium Benzoate (UNII: OJ245FE5EU)	
INGR	Sodium Chlorite (UNII: G538EBV4VF)	
INGR	Benzoic Acid (UNII: 8SKN0B0MIM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		01/01/2024	

Part 2 of 2

SMARTMOUTH GUM HEALTH SOLUTION 2

cetylpyridinium chloride liquid

Product Information

Item Code (Source) NDC:76357-599

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Cetylpyridinium Chloride (UNII: D9OM4SK49P) (Cetylpyridinium - UNII:CUB7J10JV3)	Cetylpyridinium Chloride	500 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
Poloxamer 407 (UNII: TUF2IVW3M2)	
Propylene Glycol (UNII: 6DC9Q167V3)	
ALOE (UNII: V5VD430YW9)	
POLOXAMER 124 (UNII: 1S66E28KXA)	
Zinc Chloride (UNII: 86Q357L16B)	
SODIUM (UNII: 9NEZ333N27)	
Benzoic Acid (UNII: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
Sodium Chloride (UNII: 451W47IQ8X)	
Benzyl Alcohol (UNII: LKG8494WBH)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	MINT (Mild Mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76357-599-02	237 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	01/01/2024	

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OTC Monograph Drug	M022	01/01/2024	

Revised: 12/2023

Triumph Pharmaceuticals, Inc.