

**SMARTMOUTH CLINICAL GUM AND PLAQUE FORMULA- cetylpyridinium chloride  
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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**SmartMouth™ Mouthwash  
Gum & Plaque 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**

- Adults and children 12 years of age and older: vigorously swish 20 milliliters 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.

**Other information**

- This rinse is not intended to replace brushing or flossing.

**Inactive Ingredients**

Solution 1: Purified Water, Sodium Benzoate, Sodium Chlorite, and Benzoic Acid

Solution 2: Purified Water, Glycerin, Poloxamer 407, Propylene Glycol, 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 or comments**

**1-800-492-7040**

DISTRIBUTED BY:  
TRIUMPH PHARMACEUTICALS INC.  
ST. LOUIS, MISSOURI 63114

**PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label**

Both Liquids with a Single Pour

H<sub>2</sub>S ELIMINATOR<sup>∞</sup> & Zn<sup>+2</sup> ACTIVATOR

smart  
mouth<sup>™</sup>  
OTC

Activates Zinc Ions  
Blocks Sulfur Gas

Clinical DDS<sup>™</sup>

ACTIVATED ORAL RINSE<sup>™</sup>

PRESCRIPTION STRENGTH<sup>+</sup>  
Gingivitis & Bleeding Gums Protection

24 HR  
BAD BREATH  
PREVENTION\*

AM RINSE = ALL DAY CLEAN BREATH  
PM RINSE = ELIMINATES MORNING BREATH

GUARANTEED<sup>†</sup>

PATENTED FORMULA • DENTIST DEVELOPED

CLEAN MINT • NO AFTERTASTE • ALCOHOL FREE • SAFE FOR DIABETICS • 16 FL. OZ. (473 mL)



*Both Liquids with a Single Pour*

**H<sub>2</sub>S ELIMINATOR<sup>OTC</sup> & Zn<sup>+2</sup> ACTIVATOR**



**Clinical DDS<sup>™</sup>**  
ACTIVATED ORAL RINSE<sup>™</sup>

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Gingivitis & Bleeding Gums Protection

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PARABEN FREE

Rx STRENGTH\*

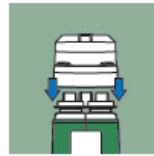
### WHY 2 SEPARATE SOLUTIONS?

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.

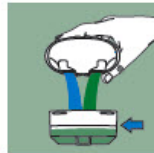
### STORE BOTTLE UPRIGHT • DO NOT SQUEEZE



**STEP 1**  
REMOVE & DISCARD  
GREEN SPACER  
& FOIL SEAL  
(NOT FOR TRAVEL)



**STEP 2**  
PUSH DOWN  
FIRMLY WITH  
PALM TO  
FULLY SECURE  
SPOUT & CUP



**STEP 3**  
POUR TO  
LINE ON CUP



**STEP 4**  
RINSE,  
GARGLE &  
SPIT OUT.



**NOT FOR TRAVEL AFTER OPENING**

Travel Size Options Available at [SmartMouth.com](http://SmartMouth.com)

DRUG FACTS	Purpose
Active Ingredient Cetylpyridinium Chloride 0.05% (when mixed as directed)	Anti-gingivitis/Anti-plaque
<b>Uses:</b> Helps prevent and reduce plaque and gingivitis. Helps control plaque bacteria that contribute to the development of gingivitis and bleeding gums.	
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<b>Directions:</b> •Adults and children 12 years of age and older: vigorously swish 20 milliliters 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.	
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<b>Questions or comments: 1-800-492-7040</b>	

\*Prescription strength gingivitis & bleeding gums protection without a prescription

**For 24 Hr Bad Breath Prevention, Rinse 2x Daily After Brushing & Flossing.**  
Use Immediately After Pouring To Ensure Dual Formula Activation.

With Regular, Twice-daily Rinsing, You Should Experience Maximum Effectiveness Within 1-2 Weeks. Re-rinsing Is Recommended After Eating Foods Containing Onion Or Garlic.

∞Eliminates H<sub>2</sub>S and all other volatile sulfur compounds (VSCs) in the mouth.

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.

TREATING OR PREVENTING ORAL HEALTH PROBLEMS BY USING SMARTMOUTH™

**\*SATISFACTION GUARANTEE:** If you are not completely satisfied with SmartMouth™ 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.



**SMARTMOUTH™**  
ORAL HEALTH LABORATORIES

QUESTIONS OR COMMENTS?

CALL 1-800-492-7040

WWW.SMARTMOUTH.COM

PATENT SMARTMOUTH.COM/PATENTS

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ST. LOUIS, MISSOURI 63141  
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PLEASE RECYCLE



## **PRINCIPAL DISPLAY PANEL - 946 mL Bottle Label**

Both Liquids with a Single Pour

**H<sub>2</sub>S ELIMINATOR<sup>∞</sup> & Zn<sup>+2</sup> ACTIVATOR**

smart  
mouth™  
OTC

Activates Zinc Ions  
Blocks Sulfur Gas

Clinical DDS™

ACTIVATED ORAL RINSE™

PRESCRIPTION STRENGTH<sup>+</sup>

Gingivitis & Bleeding Gums Protection

24 HR

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GUARANTEED<sup>†</sup>

PATENTED FORMULA • DENTIST DEVELOPED

CLEAN MINT • NO AFTERTASTE • ALCOHOL FREE • SAFE FOR DIABETICS • 32 FL. OZ. (946 mL)



Both Liquids with a Single Pour

**H<sub>2</sub>S ELIMINATOR<sup>∞</sup> & Zn<sup>+2</sup> ACTIVATOR**



**Clinical DDS™**  
ACTIVATED ORAL RINSE™

**PRESCRIPTION STRENGTH\***  
Gingivitis & Bleeding Gums Protection

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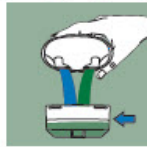
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SMARTMOUTH<sup>™</sup>  
ORAL HEALTH LABORATORIES

QUESTIONS OR COMMENTS?

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PATENT [SMARTMOUTH.COM/PATENTS](http://SMARTMOUTH.COM/PATENTS)

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# SMARTMOUTH CLINICAL GUM AND PLAQUE FORMULA

cetylpyridinium chloride kit

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76357-250
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76357-250-09	1 in 1 CELLO PACK	09/28/2015	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	236.5 mL
Part 2	1 BOTTLE, PLASTIC	236.5 mL

## Part 1 of 2

### SMARTMOUTH GUM AND PLAQUE SOLUTION 1

mouthwashes and breath fresheners (liquids and sprays)

## Product Information

Route of Administration	DENTAL
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## 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)	

## Product Characteristics

color	WHITE	C48325
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		236.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		09/28/2015	

## Part 2 of 2

### SMARTMOUTH GUM AND PLAQUE SOLUTION 2 MINT

cetylpyridinium chloride liquid

## Product Information

Route of Administration DENTAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Cetylpyridinium Chloride (UNII: D9OM4SK49P) (Cetylpyridinium - UNII:CUB7JI0JV3)	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)	
Poloxamer 124 (UNII: 1S66E28KXA)	
Zinc Chloride (UNII: 86Q357L16B)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Benzoic Acid (UNII: 8SKN0B0MIM)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sodium Chloride (UNII: 451W47IQ8X)	
Benzyl Alcohol (UNII: LKG8494WBH)	
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
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1	236.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
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### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	09/28/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	09/28/2015	

## SMARTMOUTH CLINICAL GUM AND PLAQUE FORMULA

cetylpyridinium chloride kit

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76357-255
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76357-255-01	1 in 1 CELLO PACK	02/01/2018	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	473 mL
Part 2	1 BOTTLE, PLASTIC	473 mL

### Part 1 of 2

## SMARTMOUTH GUM AND PLAQUE SOLUTION 1

mouthwashes and breath fresheners (liquids and sprays)

### Product Information

Route of Administration	DENTAL
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### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	Water (UNII: 059QF0KO0R)	
INGR	Sodium Benzoate (UNII: OJ245FE5EU)	

INGR	<b>Sodium Chlorite</b> (UNII: G538EBV4VF)	
INGR	<b>Benzoic Acid</b> (UNII: 8SKN0B0MM)	

### Product Characteristics

<b>color</b>	WHITE	C48325
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		02/01/2018	

## Part 2 of 2

### SMARTMOUTH GUM AND PLAQUE SOLUTION 2 MINT

cetylpyridinium chloride liquid

### Product Information

<b>Route of Administration</b>	DENTAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Cetylpyridinium Chloride</b> (UNII: D9OM4SK49P) (Cetylpyridinium - UNII:CUB7JI0JV3)	Cetylpyridinium Chloride	500 mg in 20 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Poloxamer 407</b> (UNII: TUF2IVW3M2)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Poloxamer 124</b> (UNII: 1S66E28KXA)	
<b>Zinc Chloride</b> (UNII: 86Q357L16B)	
<b>Sodium Benzoate</b> (UNII: OJ245FE5EU)	
<b>Benzoic Acid</b> (UNII: 8SKN0B0MIM)	
<b>Saccharin Sodium</b> (UNII: SB8ZUX40TY)	
<b>Sodium Chloride</b> (UNII: 451W47IQ8X)	

<b>Benzyl Alcohol</b> (UNII: LKG8494WBH)	
<b>D&amp;C Yellow No. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C Blue No. 1</b> (UNII: H3R47K3TBD)	

<b>Product Characteristics</b>			
<b>Color</b>	GREEN	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (mint vanilla)	<b>Imprint Code</b>	
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part356	02/01/2018		

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part356	02/01/2018		

**Labeler** - Triumph Pharmaceuticals Inc. (017853461)