

**SMARTMOUTH MOUTHWASH CLINICAL DDS 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  
Clinical DDS™ 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 (5 pumps from each bottle) 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**

SMARTMOUTH™ & SMART MOUTH™  
ARE TRADEMARKS OF & DISTRIBUTED BY:  
TRIUMPH PHARMACEUTICALS INC. • ST. LOUIS, MISSOURI 63141

**PRINCIPAL DISPLAY PANEL - Kit Cello Pack**

**smart  
mouth™**

**Clinical DDS™**

***2-Bottle Activated System***

**ELIMINATES**  
Existing Sulfur Gas

**BLOCKS**  
New Sulfur Gas

Combine  
in Cup to  
**ACTIVATE**

**CLEAN MINT**

TOTAL  
NET WT.  
32 FL. OZ.  
(960 mL)

SMART  
MOUTH

Clinical DDS™

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## WHY 2 SEPARATE SOLUTIONS?

The power of SmartMouth™ is in the ACTIVATION. Pump the two solutions together to activate the Smart-Zinc™, which eliminates and prevents bad breath for 24 hours with twice daily use.

### NOTE

If spilled on fabric, wash out immediately. Do not use this product if the tamper-evident seal is loose, missing or broken. Keep out of reach of children. Do not discard these instructions.

### †SATISFACTION GUARANTEE

If you are not completely satisfied with Smart Mouth™ 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™



**24HR**  
BAD BREATH  
PREVENTION\*

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QUESTIONS OR COMMENTS?  
CALL 1.800.492.7040 OR VISIT WWW.SMARTMOUTH.COM

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**Other information:** • This rinse is not intended to replace brushing or flossing.

Inactive Ingredients:

Solution 1: Purified Water, Sodium Benzoate, Sodium Chloride, and Benzoic Acid  
Solution 2: Purified Water, Glycerin, Poloxamer 407, Propylene Glycol, Poloxamer 128,  
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

**\*For 24 Hour 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.

## SMARTMOUTH MOUTHWASH CLINICAL DDS FORMULA

cetylpyridinium chloride kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76357-285
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76357-285-01	1 in 1 CELLO PACK; Type 0: Not a Combination Product	10/01/2018	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	480 mL
Part 2	1 BOTTLE, PLASTIC	480 mL

### Part 1 of 2

# SMARTMOUTH CLINICAL DDS SOLUTION 1

mouthwashes and breath fresheners (liquids and sprays)

## Product Information

## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>Water</b> (UNII: 059QF0K00R)	
INGR	<b>Sodium Benzoate</b> (UNII: OJ245FE5EU)	
INGR	<b>Sodium Chlorite</b> (UNII: G538EBV4VF)	
INGR	<b>Benzoic Acid</b> (UNII: 8SKN0B0MIM)	

## Product Characteristics

color	WHITE	C48325
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		480 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		10/01/2018	

## Part 2 of 2

# SMARTMOUTH CLINICAL DDS SOLUTION 2 MINT

cetylpyridinium chloride liquid

## Product Information

Route of Administration	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
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
1		480 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
OTC MONOGRAPH NOT FINAL	part356	10/01/2018	

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