

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.

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

H₂S ELIMINATOR[∞] & Zn⁺² ACTIVATOR

smart
mouth™
OTC

Activates Zinc Ions
Blocks Sulfur Gas

Clinical DDS™
ACTIVATED ORAL RINSE™

PRESCRIPTION STRENGTH⁺
Gingivitis & Bleeding Gums Protection

24HR
BAD BREATH
PREVENTION*

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

GUARANTEED[†]

PATENTED FORMULA • DENTIST DEVELOPED

CLEAN MINT • NO AFTERTASTE
ALCOHOL FREE • SAFE FOR DIABETICS

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



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QUESTIONS OR COMMENTS?

CALL 1.800.492.7040 OR VISIT WWW.SMARTMOUTH.COM
 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.

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. Use within 6 months after opening.

SATISFACTION GUARANTEE
 For 24 Hr Bad Breath Prevention, Please Use Daily After Brushing & Flossing.
 Contains 1% and other water-soluble compounds (WSC) in the mouth.
 Prescription strength gingivitis & bleeding gums protection without a prescription.
 Use immediately after flossing to ensure full formula activation. With regular, twice-daily flossing, you should experience Maximum Effectiveness Within 24 Weeks. Re-flossing & Recommended After Eating Foods Containing Onion or Garlic.

Directions - Use after your normal brushing and flossing routine.
 Adults and children 12 years of age & older: Vigorously swish 20 mL of rinse (5 pumps from each bottle) twice a day for 30 seconds and then spit out. Do not swallow.
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 Children under 6 years of age: do not use.

Inactive Ingredients Solution 1: Purified Water, Sodium Benzoate, Sodium Chloride, 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.

Warnings
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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.

PARABEN FREE
RX STRENGTH

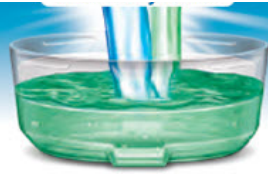


SMART MOUTH™
 ORAL HEALTH LABORATORIES

H₂S ELIMINATOR™ & Zn²⁺ ACTIVATOR



Activates Zinc Ions
 Blocks Sulfur Gas



Clinical DDS™

ACTIVATED ORAL RINSE™

PRESCRIPTION STRENGTH®
Gingivitis & Bleeding Gums Protection

24HR BAD BREATH
PREVENTION®

☀ **AM RINSE** = ALL DAY CLEAN BREATH
🌙 **PM RINSE** = ELIMINATES MORNING BREATH

GUARANTEED†

🌿 CLEAN MINT • NO AFTERTASTE
ALCOHOL FREE • SAFE FOR DIABETICS

PATENTED FORMULA • DENTIST DEVELOPED

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

2-Bottle Activated System

ELIMINATES
Existing Sulfur Gas →

← **BLOCKS**
New Sulfur Gas

Combine
in Cup to
ACTIVATE



PRESCRIPTION STRENGTH®
Gingivitis & Bleeding Gums Protection

24HR BAD BREATH
PREVENTION®

PRESCRIPTION STRENGTH®
Gingivitis & Bleeding Gums Protection

24HR BAD BREATH
PREVENTION®



SMARTMOUTH MOUTHWASH CLINICAL DDS FORMULA

cetylpyridinium chloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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	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		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
Cetylpyridinium Chloride (UNII: D9OM4SK49P) (Cetylpyridinium - UNII:CUB7J10JV3)	Cetylpyridinium Chloride	500 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C00X)	
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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OTC MONOGRAPH NOT FINAL	part356	10/01/2018	

Labeler - Triumph Pharmaceuticals Inc. (017853461)

Revised: 2/2023

Triumph Pharmaceuticals Inc.