SMARTMOUTH ADVANCE CLINICAL DDS FORMULA MINT- cetylpyridinium chloride

Triumph Pharmaceuticals, Inc.

SmartMouth™ Advance Clinical DDS™ Formula Mint 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 (one sample packet) 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™ IS A TRADEMARK OF AND DISTRIBUTED BY: TRIUMPH PHARMACEUTICALS INC. ST. LOUIS, MISSOURI 63141

PRINCIPAL DISPLAY PANEL - Kit Pouch

MIXES TO ACTIVATE 2 Powerful Solutions

smart mouth™

Clinical

Zinc Activated Oral Rinse™

24 HOUR

BAD BREATH
PREVENTION
WITH A MORNING & EVENING RINSE

Prescription Strength Formula+

Gingivitis & Bleeding Gums Protection

Dentist Recommended

Zinc Promotes Oral Health & Boosts Immunity

CLEAN MINT • 0.68 FL. OZ. [20 mL] • ALCOHOL FREE • SAFE FOR PEOPLE WITH DIABETES





Zinc Activated Oral Rinse

BAD BREATH PREVENTION HOUR

Prescription Strength Formula

Gingivitis & Bleeding Gums Protection Dentist Recommended

Zinc Promotes Oral Health & Boosts Immunity

CLEAN MINT + 0.68 FL. OZ. [20 mL] + ALCOHOL FREE + SAFE FOR PEOPLE WITH DIABETES



ONE-TIME USE.

The power of SmartMouth™ is in the ACTIVATION. Mix the two solutions to activate the Smart-Zinc™ technology, which eliminates and prevents bad breath for at least 12 hours with each rinse. Rinse in the morning for fresh breath all day; rinse at night and wake up without bad breath... NO MORNING BREATH! No other mouthwash can do this!

Drug Facts

Active Ingredient Purpose
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- Directions Use after your normal brushing and flossing routine
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 Children under 6 years of age: Do not use unless directed by a healthcare profes

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. m Saccharin, Sodium Chloride, Benzyl Alcohol, D&C Yellow No. 10, FD&C Blue No.

Questions? 1-800-492-7040 Use Immediately After Pouring To Ensure Dual Formula Activation

*Prescription strength gingivitis & bleeding gums protection without a prescription

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

PLEASE NOTE: If packing in luggage, store in a sealed plastic bag. If spilled on fabric, wash out immediately. Keep out of reach of children.



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WWW.SMARTMOUTH.COM PATENT SMARTMOUTH.COM/PATENTS

SMARTMOUTH ADVANCE CLINICAL DDS FORMULA MINT

cetylpyridinium chloride kit

Product Information

HUMAN OTC DRUG Item Code (Source) **Product Type** NDC:76357-230

Packaging

l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:76357-230-01	1 in 1 POUCH	12/01/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 POUCH	10 mL
Part 2	1 POUCH	10 mL

Part 1 of 2

SMARTMOUTH MOUTHWASH ADVANCE CLINICAL DDS FORMULA **SOLUTION 1 (H2S ELIMINATOR)**

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

Product Information

INGR

Route of Administration DENTAL

Other Ingredients				
Ingredient Kind	Ingredient Name	Quantity		
INGR	water (UNII: 059QF0KO0R)			
INGR	Sodium Benzoate (UNII: 0/245FE5EU)			

Benzoic Acid (UNII: 85KN0B0MIM) **INGR Sodium Chlorite** (UNII: G538EBV4VF)

COLR WHITE ()

ı	Pa	ackaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		10 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Cosmetic		12/01/2019		

Part 2 of 2

SMARTMOUTH MOUTHWASH ADVANCE CLINICAL DDS FORMULA **SOLUTION 2 (ZN PLUS 2 ACTIVATOR)**

cetylpyridinium chloride liquid

Product Information

Route of Administration DENTAL

Active Ingredier	nt/Active Moi	ietv
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Ingredient Name	Basis of Strength	Strength
	CETYLPYRIDINIUM CHLORIDE	500 mg in 20 mL

Inactive Ingredients			
Ingredient Name	Strength		
water (UNII: 059QF0KO0R)			
Sodium Benzoate (UNII: OJ245FE5EU)			
Benzoic Acid (UNII: 8SKN0B0MIM)			
Glycerin (UNII: PDC6A3C0OX)			
Poloxamer 407 (UNII: TUF2IVW3M2)			
Propylene Glycol (UNII: 6DC9Q167V3)			
Poloxamer 124 (UNII: 1S66E28KXA)			
Zinc Chloride (UNII: 86Q357L16B)			
Sodium (UNII: 9NEZ 333N27)			
Saccharin Sodium (UNII: SB8ZUX40TY)			
Sodium Chloride (UNII: 451W47IQ8X)			
Benzyl Alcohol (UNII: LKG8494WBH)			

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		10 mL in 1 POUCH; 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	12/01/2019		

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OTC monograph drug	M022	12/01/2019		

Labeler - Triumph Pharmaceuticals, Inc. (017853461)