

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

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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



SMARTMOUTH ADVANCE CLINICAL DDS FORMULA MINT

cetylpyridinium chloride kit

Product Information

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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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

Route of Administration DENTAL

Other Ingredients

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

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
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 Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPIRIDINIUM - UNII:CUB7JI0JV3)	CETYLPIRIDINIUM CHLORIDE	500 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
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: 9NEZ333N27)	
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	

Marketing Information

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OTC monograph drug	M022	12/01/2019	

Labeler - Triumph Pharmaceuticals, Inc. (017853461)