

SMARTMOUTH CLINICAL GUM AND PLAQUE FORMULA- cetylpyridinium chloride

Triumph Pharmaceuticals Inc.

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

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ST. LOUIS, MISSOURI 63114

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label - Oral Rinse

MIXES TO ACTIVATE
2 Powerful Solutions

smart
mouth™

Clinical
Zinc Activated Oral Rinse™

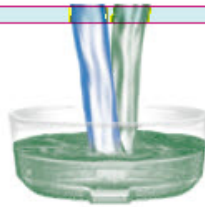
24
HOUR

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 • 16 FL. OZ. (473 mL) • ALCOHOL FREE • SAFE FOR PEOPLE WITH
DIABETES



MIXES TO ACTIVATE
2 Powerful Solutions



Clinical

Zinc Activated Oral Rinse*



**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 • 16 FL. OZ. [473 mL] • ALCOHOL FREE • SAFE FOR PEOPLE WITH DIABETES

← 2mm Art Underlap - background elements only, no critical artwork →

↓
TO OPEN
Tear Down
Along
Perforated
Lines

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

Lift cup and spout to remove and discard green spacer and foil seal



STEP 2

Replace cup and spout and push down with palm to secure



STEP 3

Remove cup and pour to line



STEP 4

Rinse, gargle & spit out



NOT FOR TRAVEL AFTER OPENING

Travel Size Options Available at SmartMouth.com

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

- Use after your normal brushing and flossing routine
- Adults and children 12 years of age & older: vigorously swish 20 mL 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.

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? 1-800-492-7040

Use Immediately After Pouring To Ensure Dual Formula Activation.

*Prescription strength gingivitis & bleeding gums protection without a prescription

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.

*SATISFACTION GUARANTEE:

For complete guarantee terms, visit <https://smartmouth.com/satisfaction-guarantee/>



SMARTMOUTH™
ORAL HEALTH LABORATORIES

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NO ARTWORK - CLEAR

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label - Breath Rinse

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⁺

ANTI-PLAQUE

ANTI-GINGIVITIS

CLEAN MINT • 16 FL. OZ. (473 mL) • ALCOHOL FREE

↓
TO OPEN
Tear Down
Along
Perforated
Lines



MIXES TO ACTIVATE
2 Powerful Solutions



NOT FOR TRAVEL AFTER OPENING
Find Travel Packs @SmartMouth.com

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 • Use after your normal brushing and flossing routine • Adults and children 12 years of age & older: vigorously swish 20 mL 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 unless directed by a healthcare professional.	
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	

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

⁺Prescription strength gingivitis & bleeding gums protection without a prescription

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.

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

STEP 1

Lift cup and spout to discard green spacer and seal.



STEP 2

Replace cup and spout and push down with palm to secure



Spout Should Face Front of Bottle

STEP 3

Remove cup and pour to line



STEP 4

Rinse, gargle & spit out



Clinical

Zinc Activated Breath Rinse™

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.

✓ Dentist Recommended

✓ Safe For People with Diabetes



**BAD BREATH
PREVENTION**
WITH A MORNING & EVENING RINSE

Prescription Strength⁺

ANTI-PLAQUE

ANTI-GINGIVITIS

QUESTIONS OR COMMENTS?
CALL 1-800-492-7040
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SMARTMOUTH™
ORAL HEALTH LABORATORIES



CLEAN MINT • 16 FL. OZ. (473 mL) • ALCOHOL FREE

PRINCIPAL DISPLAY PANEL - 946 mL Bottle Label

MIXES TO ACTIVATE
2 Powerful Solutions

smart
mouth™

Clinical
Zinc Activated Oral Rinse™

24
HOUR

BAD BREATH
PREVENTION
WITH A MORNING & EVENING RINSE

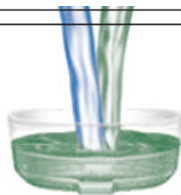
Prescription Strength Formula⁺

Gingivitis & Bleeding Gums Protection

Dentist Recommended

Zinc Promotes Oral Health & Boosts Immunity

CLEAN MINT • 32 FL. OZ. (946 mL) • ALCOHOL FREE • SAFE FOR PEOPLE WITH
DIABETES



MIXES TO ACTIVATE
2 Powerful Solutions



Clinical

Zinc Activated Oral Rinse™



**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 - 32 FL. OZ. (946 mL) - ALCOHOL FREE - SAFE FOR PEOPLE WITH DIABETES



TO OPEN
Tear Down
Along
Perforated

Lines

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
Lift cup and spout to remove and discard green spacer and foil seal



STEP 2
Replace cup and spout and push down with palm to secure



STEP 3
Remove cup and spout to line



STEP 4
Rinse, gargle & spit out



NOT FOR TRAVEL AFTER OPENING

Travel Size Options Available at SmartMouth.com

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

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

*Prescription strength gingivitis & bleeding gums protection without a prescription

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.

*SATISFACTION GUARANTEE:

For complete guarantee terms, visit <https://smartmouth.com/satisfaction-guarantee/>



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PLEASE RECYCLE



PRINCIPAL DISPLAY PANEL - 296 mL Bottle Label

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 • 10 FL. OZ. (296 mL) • ALCOHOL FREE • SAFE FOR PEOPLE WITH
DIABETES



MIXES TO ACTIVATE
2 Powerful Solutions



Clinical

Zinc Activated Oral Rinse™



**BAD BREATH
PREVENTION**

WITH A MORNING & EVENING RINSE

Prescription Strength Formula*

Gingivitis & Bleeding Gums Protection

Dentist Recommended

Zinc Promotes Oral Health & Boosts Immunity

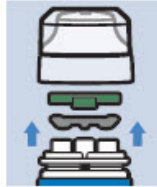
CLEAN MINT • 10 FL. OZ. [296 mL] • ALCOHOL FREE • SAFE FOR PEOPLE WITH DIABETES

HIGH DISTORTION AREA

HIGH DISTORTION AREA

TO OPEN
Tear Down
Along
Perforated

STORE BOTTLE UPRIGHT. DO NOT SQUEEZE.



STEP 1

Lift cup and spout to remove and discard green spacer and foil seal



STEP 2

Replace cup and spout and push down with palm to secure



STEP 3

Remove cup and pour to line



STEP 4

Rinse, gargle & spit out



NOT FOR TRAVEL AFTER OPENING

Travel Size Options Available at SmartMouth.com

Drug Facts

Active Ingredient

Cetylpyridinium Chloride 0.05% (when mixed as directed). **Purpose** Anti-gingivitis/Anti-plaque

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Questions? 1-800-492-7040

Use Immediately After Pouring To Ensure Dual Formula Activation.

*Prescription strength gingivitis & bleeding gums protection without a prescription

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.

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



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ORAL HEALTH LABORATORIES

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PLEASE RECYCLE



PRINCIPAL DISPLAY PANEL - 320 mL Bottle Label

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 • 10.82 FL. OZ. (320 mL) • ALCOHOL FREE • SAFE FOR PEOPLE WITH
DIABETES



MIXES TO ACTIVATE
2 Powerful Solutions



Clinical

Zinc Activated Oral Rinse*



**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 • 10.82 FL. OZ. [320 mL] • ALCOHOL FREE • SAFE FOR PEOPLE WITH DIABETES

↓
TO OPEN
Tear Down
Along
Perforated
Lines

STORE BOTTLE UPRIGHT. DO NOT SQUEEZE.



STEP 1

Lift cup and spout to remove and discard green spacer and foil seal



STEP 2

Replace cup and spout and push down with palm to secure



STEP 3

Remove cap and pour to line



STEP 4

Rinse, gargle & spit out



NOT FOR TRAVEL AFTER OPENING

Travel Size Options Available at SmartMouth.com

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.

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Directions

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- Children under 6 years of age: do not use.

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? 1-800-492-7040

Use Immediately After Pouring To Ensure Dual Formula Activation.

*Prescription strength gingivitis & bleeding gums protection without a prescription

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.

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

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ST. LOUIS, MISSOURI 63141 632022

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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) [oral products]

Product Information

Route of Administration	DENTAL
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Other Ingredients

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

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:CUB7JJOJV3)	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		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
OTC Monograph Drug	M022	09/28/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	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) [oral products]

Product Information

Route of Administration	DENTAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
COLR	White ()	
INGR	Water (UNII: 059QF0KO0R)	
INGR	Sodium Benzoate (UNII: OJ245FE5EU)	
INGR	Sodium Chlorite (UNII: G538EBV4VF)	

INGR	Benzoic Acid (UNII: 8SKN0B0MIM)	
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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

Route of Administration DENTAL

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: 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		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
OTC Monograph Drug	M022	02/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	02/01/2018	

SMARTMOUTH CLINICAL GUM AND PLAQUE FORMULA

cetylpyridinium chloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76357-210
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76357-210-01	1 in 1 CELLO PACK	12/02/2020	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	296 mL
Part 2	1 BOTTLE, PLASTIC	296 mL

SMARTMOUTH GUM AND PLAQUE SOLUTION 1

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

Product Information

Route of Administration	DENTAL
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Other Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		296 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		12/02/2020	

Part 2 of 2

SMARTMOUTH GUM AND PLAQUE SOLUTION 2 MINT

cetylpyridinium chloride liquid

Product Information

Item Code (Source)	NDC:76357-290
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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: 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	NDC:76357-290-01	296 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 Drug	M022	12/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	12/02/2020	

SMARTMOUTH CLINICAL GUM AND PLAQUE FORMULA

cetylpyridinium chloride kit

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:76357-211
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76357-211-01	1 in 1 CELLO PACK	01/01/2023	
Quantity of Parts				
Part #	Package Quantity		Total Product Quantity	
Part 1	1 BOTTLE, PLASTIC		160 mL	
Part 2	1 BOTTLE, PLASTIC		160 mL	
Part 1 of 2				
SMARTMOUTH GUM AND PLAQUE SOLUTION 1				
mouthwashes and breath fresheners (liquids and sprays) [oral products]				
Product Information				
Route of Administration		DENTAL		
Other Ingredients				
Ingredient Kind		Ingredient Name		Quantity
COLR		White ()		
INGR		Water (UNII: 059QF0KO0R)		
INGR		Sodium Benzoate (UNII: OJ245FE5EU)		
INGR		Sodium Chlorite (UNII: G538EBV4VF)		
INGR		Benzoic Acid (UNII: 8SKN0B0MIM)		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		160 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			01/01/2023	

Part 2 of 2

SMARTMOUTH GUM AND PLAQUE SOLUTION 2 MINT

cetylpyridinium chloride liquid

Product Information

Item Code (Source)	NDC:76357-291
Route of Administration	DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Cetylpyridinium Chloride (UNII: D9OM4SK49P) (Cetylpyridinium - UNII:CUB7JIOJV3)	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		160 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 Drug	M022	01/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	01/01/2023	

Labeler - Triumph Pharmaceuticals Inc. (017853461)

Revised: 12/2023

Triumph Pharmaceuticals Inc.