

**SMARTMOUTH MOUTHWASH SMARTMOUTH MOUTH SORE ZINC ACTIVATED
FORMULA- menthol, unspecified form
Triumph Pharmaceuticals, Inc.**

**SmartMouth™ Mouthwash
Mouth Sore Solution 1**

Drug Facts

Active Ingredient

Menthol 0.2% (when mixed as directed)

Purpose

Oral Pain Reliever

Uses

For the temporary relief of occasional minor irritation, pain, sore mouth, and sore throat.
For the temporary relief of pain associated with:

- Canker sores
- Minor dental procedures
- Minor irritation or injury of the mouth or gums
- Minor irritation of the mouth and gums caused by dentures or orthodontic appliances

Warnings

Do not use this product for more than 7 days unless directed by a dentist or healthcare provider

When using this product do not swallow

- do not exceed recommended dosage

Stop use and see your physician promptly if

- swelling, rash or fever develops
- irritation, pain or redness persists or worsens
- sore mouth symptoms do not improve in 7 days

Keep out of reach of children. 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 & older:** Swish 20mL of rinse (pour to indicator line on cup) around the mouth over the affected area for at least 1 minute, gargle and then spit out. Use up to 4 times daily or as directed by a dentist or doctor.
- **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 Chlorite, and Benzoic Acid. Solution 2: Purified Water, Sorbitol, Poloxamer 407, Glycerin, Propylene Glycol, Poloxamer 124, Zinc Chloride, Flavor, Sodium Benzoate, Benzyl Alcohol, Sodium Saccharin, Peppermint Oil, Benzoic Acid, Aloe Extract, Sodium Chloride, D&C Yellow No. 10, FD&C Blue No. 1

Questions?

1-800-492-7040

DISTRIBUTED BY:
TRIUMPH PHARMACEUTICALS INC.
ST. LOUIS, MISSOURI 63141

PRINCIPAL DISPLAY PANEL - Kit Bottle Label

NEW &
IMPROVED
POUR

MIXES TO
ACTIVATE
2 Powerful Solutions

BLOCKS
ODORS

FRESHENS
BREATH

smart
mouth™

Mouth Sore

Scientifically Proven
Smart-Zinc™ Technology

24
HOUR

BAD BREATH
PREVENTION
WITH A MORNING & EVENING RINSE

Oral Pain Relief For

CANKER SORES & CHEEK BITES

GUM, BRACES & DENTURE IRRITATION

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

Zinn Clear

NEW & IMPROVED POUR

MIXES TO ACTIVATE
2 Powerful Solutions

BLOCKS ODORS



FRESHENS BREATH

corner

STEP 1

Open the green cap, pour to the 10mL mark on the provided cup, then close the green cap



STEP 2

Open the blue cap, pour to the 20mL mark on the cup, then close the blue cap



STEP 3

Vigorously swish for 60 seconds, gargle & spit out



Mouth Sore

Scientifically Proven Smart-Zinc™ Technology



BAD BREATH PREVENTION

WITH A MORNING & EVENING 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

Zinn Clear

QUESTIONS OR COMMENTS?
CALL 1-800-492-7040
WWW.SMARTMOUTH.COM
PATENT SMARTMOUTH.COM/PATENTS

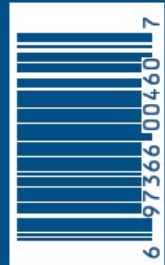
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TRIUMPH PHARMACEUTICALS INC.
ST. LOUIS, MISSOURI 63141
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SMARTMOUTH™
ORAL HEALTH LABORATORIES

Oral Pain Relief For

CANKER SORES & CHEEK BITES

GUM, BRACES & DENTURE IRRITATION



High Distortion - AVOID CRITICAL COPY

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

TO OPEN
Tea Down
Center back panel

corner

Penetrates
 Approximate
 Safety Seal Approaches Your Protection

89



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

Drug Facts	
Active Ingredient Menthol 0.2% (when mixed as directed)	Purpose Oral Pain Reliever
Uses For the temporary relief of occasional minor irritation, pain, sore mouth, and sore throat. For the temporary relief of pain associated with: • Canker sores • Minor dental procedures • Minor irritation or injury of the mouth or gums • Minor irritation of the mouth and gums caused by dentures or orthodontic appliances	
Warnings Do not use this product for more than 7 days unless directed by a dentist or healthcare provider When using this product do not swallow • do not exceed recommended dosage Stop use and see your physician promptly if • swelling, rash or fever develops • irritation, pain or redness persists or worsens • sore mouth symptoms do not improve in 7 days Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away	
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Inactive Ingredients Solution 1: Purified Water, Sodium Benzoate, Sodium Chlorite, and Benzoic Acid. Solution 2: Purified Water, Sorbitol, Poloxamer 407, Glycerin, Propylene Glycol, Poloxamer 124, Zinc Chloride, Flavor, Sodium Benzoate, Benzyl Alcohol, Sodium Saccharin, Peppermint Oil, Benzoic Acid, Aloe Extract, Sodium Chloride, D&C Yellow No. 10, FD&C Blue No. 1	
Questions? 1-800-492-7040 Use Immediately After Pouring To Ensure Dual Formula Activation.	
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 if plastic wrap around the cup (safety seal) is broken. Use within 6 months after opening.	
SATISFACTION GUARANTEE: For complete guarantee terms, visit https://smartmouth.com/satisfaction-guarantee/	

SMARTMOUTH MOUTHWASH SMARTMOUTH MOUTH SORE ZINC ACTIVATED FORMULA

menthol, unspecified form kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76357-419
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76357-419-00	1 in 1 CARTON	01/01/2025	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	237 mL
Part 2	1 BOTTLE	237 mL

Part 1 of 2

SMARTMOUTH MOUTHWASH MOUTH SORE 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
INGR	WATER (UNII: 059QF0KO0R)	
INGR	Sodium Benzoate (UNII: OJ245FE5EU)	
INGR	Sodium Chlorite (UNII: G538EBV4VF)	
INGR	Benzoic Acid (UNII: 8SKN0B0MIM)	
COLR	WHITE ()	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		01/01/2025	

Part 2 of 2

SMARTMOUTH MOUTHWASH MOUTH SORE SOLUTION 2

menthol, unspecified form liquid

Product Information

Item Code (Source) NDC:76357-489

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
Poloxamer 407 (UNII: TUF2IVW3M2)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Aloe (UNII: V5VD430YW9)	
Poloxamer 124 (UNII: 1S66E28KXA)	
Zinc Chloride (UNII: 86Q357L16B)	
Sodium (UNII: 9NEZ333N27)	
Benzoic Acid (UNII: 8SKN0B0MIM)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sodium Chloride (UNII: 451W47IQ8X)	
Benzyl Alcohol (UNII: LKG8494WBH)	
Sorbitol (UNII: 506T60A25R)	
Peppermint (UNII: V95R5KMY2B)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	MINT (Mild Mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76357-489-02	237 mL in 1 BOTTLE; 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	01/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M022	01/01/2025	

Labeler - Triumph Pharmaceuticals, Inc. (017853461)

Revised: 12/2024

Triumph Pharmaceuticals, Inc.