

**THERABREATH PLAQUE CONTROL- cetylpyridinium chloride rinse  
Church & Dwight Co., 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.*

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**Therabreath™ Plaque Control**

**Drug Facts**

**Active Ingredient**

Cetylpyridinium Chloride 0.075%

**Purpose**

Antigingivitis/Antiplaque

**Uses**

- Helps prevent gingivitis, an early form of gum disease and bleeding gums
- Helps control plaque that leads to gingivitis and bleeding gums

**Warnings**

**Stop use and ask a dentist if**

- Gingivitis, bleeding, or redness persists for more than 2 weeks.
- You have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.

**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 and older | Vigorously swish 20 milliliters (4 teaspoonfuls) of rinse between your teeth twice a day for 30 seconds and then spit out. Do not swallow the rinse. |
| Children 6 years to under 12 years     | Supervise use.   |
| Children under 6                       | Do not use.  |

years

DO NOT USE.

### **Other information**

This rinse is not intended to replace brushing or flossing.

### **Inactive Ingredients**

Water, Glycerin, Poloxamer 407, Flavor, Sodium Benzoate, Sucralose

### **PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label**

ANTINGIVITIS/ANTIPLAQUE MOUTHRINSE

WITH  
50% MORE  
CPC<sup>‡</sup>

TheraBreath™

DENTIST FORMULATED

PLAQUE CONTROL

PRE-BRUSH

ORAL RINSE

HELPS FIGHT PLAQUE & GINGIVITIS FOR 24 HOURS\*

ANTI-BACTERIAL RINSE • CLEANS WHOLE MOUTH

No Alcohol • No Dyes • Non Burning

COOL MINT

16 fl. oz.  
473 mL

ANTINGINGIVITIS/ANTIPLAQUE MOUTHRINSE

#1 FASTEST GROWING MOUTHWASH BRAND IN USA\*

WITH MORE CPC

# TheraBreath™

DENTIST FORMULATED

## PLAQUE CONTROL

## PRE-BRUSH

## ORAL RINSE

HELPS FIGHT PLAQUE & GINGIVITIS FOR **24 HOURS\***  
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*Dr. Harold Katz*

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473 mL

**Here's Our Story:**

Plaque buildup happens to everybody. That's why our team created TheraBreath Plaque Control Oral Rinse for consumers who suffer from plaque issues and discomfort. This anti-bacterial formula is designed specifically for rinsing before brushing and helps fight bacteria associated with plaque, gingivitis and gum disease. Use this pre-brush solution prior to brushing and flossing, then finish with our fabulous post-brush rinses to complete the ideal oral care routine.



Dr. Harold Katz  
Dentist/Bacteriologist

**Our Guarantee To You:**

Your satisfaction with every TheraBreath product is guaranteed or your money back. If you are not completely satisfied, please contact us for refund instructions.  
 \*For plaque and gingivitis protection, use as directed.  
 †Data on file.  
 ‡Compared to TheraBreath Healthy Gums Clean Mint formula.

Keep out of the reach of children. If spilled on fabrics, wash as directed. This product was sealed with protective packaging at the laboratory. If seal is missing, do not use.  
 This rinse may cause temporary staining to the surface of the teeth. This is not harmful, and adequate brushing may prevent its occurrence.

TheraBreath is manufactured for Church & Dwight Co., Inc. Ewing, NJ 08628 U.S.A. © 2022. All rights reserved.

PHONE: 1-800-973-7374 WEB: [THERABREATH.COM](http://THERABREATH.COM)



| Drug Facts   |   |
|--|---|
| Active Ingredient  | Purpose   |
| Cetylpyridinium Chloride 0.075%  | Antigingivitis/Antiplaque   |
| <b>Uses</b>  |   |
| • Helps prevent gingivitis, an early form of gum disease and bleeding gums   |   |
| • Helps control plaque that leads to gingivitis and bleeding gums  |   |
| <b>Warnings</b>  |   |
| Stop use and ask a dentist if:   |   |
| • Gingivitis, bleeding, or redness persists for more than 2 weeks.   |   |
| • You have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease. |   |
| Keep out of reach of children under 4 years of age. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.                 |   |
| <b>Directions</b>  |   |
| Adults and Children 12 years and older   | Rinse thoroughly with 20 mL (4 teaspoons) of rinse between your teeth twice a day for 30 seconds and then spit out. Do not swallow the rinse. |
| Children 6 years to under 12 years   | Supervise use.  |
| Children under 6 years   | Do not use.   |
| <b>Other information</b>   |   |
| This rinse is not intended to replace brushing or flossing.  |   |
| <b>Inactive Ingredients:</b> Water, Glycerin, Poloxamer 407, Flavor, Sodium Benzoate, Sucralose.   |   |



ORAL RINSE

## THERABREATH PLAQUE CONTROL

cetylpyridinium chloride rinse

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:10237-259 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength        | Strength          |
|--|--------------------------|-------------------|
| <b>CETYLPIRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P) (CETYLPIRIDINIUM - UNII:CUB7J10JV3) | CETYLPIRIDINIUM CHLORIDE | 0.015 mg in 20 mL |

### Inactive Ingredients

| Ingredient Name                           | Strength |
|---|----------|
| <b>Water</b> (UNII: 059QF0KO0R)           |          |
| <b>Glycerin</b> (UNII: PDC6A3C0OX)        |          |
| <b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)   |          |
| <b>Sodium Benzoate</b> (UNII: OJ245FE5EU) |          |
| <b>Sucralose</b> (UNII: 96K6UQ3ZD4)       |          |

### Product Characteristics

| Color  | Score        |
|--------|--------------|
| Shape  | Size         |
| Flavor | Imprint Code |
|        |              |
| MINT   |              |
|        |              |

**Packaging**

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:10237-259-16 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/25/2023           |                    |

**Marketing Information**

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC MONOGRAPH NOT FINAL | part356                                  | 04/25/2023           |                    |

**Labeler** - Church & Dwight Co., Inc. (001211952)

Revised: 7/2023

Church &amp; Dwight Co., Inc.