

**THERABREATH HEALTHY GUMS ORAL RINSE- cetylpyridinium chloride rinse**  
**Dr. Harold Katz, LLC**

*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 Healthy Gums Oral Rinse**

**Active Ingredient**

Cetylpyridinium chloride 0.05%

**Purpose**

Antigingivitis/Antiplaque

**Uses**

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

**Warnings**

**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.

**Warnings**

**Stop Use and Ask a Doctor 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 or symptoms of periodontitis, a serious form of gum disease.

**Directions**

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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 under12 years	supervise use.
Children under 6 years	Do not use.

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## Other Information

This rinse is not intended to replace brushing or flossing.

## Inactive Ingredients

Water, Glycerin, Poloxamer 407, Flavor, Sucralose

## TheraBreath Healthy Gums Oral Rinse

ANTINGIVITIS/ ANTIPLAQUE MOUTHRINSE
Made just for you by THERABREATH

**POTENT CPC FORMULA**

**PROFESSIONAL FORMULA**

# TheraBreath®

**PERIODONTIST FORMULATED**

## HEALTHY GUMS

# ORAL RINSE

**FIGHTS GINGIVITIS FOR 24 HOURS\***

**PROTECTS FROM PLAQUE & TARTAR • FRESHENS BREATH**

Reduces Occurrence of Gum Disease & Bleeding Gums  
No Alcohol, No Artificial Flavors or Colors

*Dr. Harold Katz*

**CLEAN MINT**

**Here's Our Story:**

Healthy gums are the foundation of a healthy mouth. That's why Dr. Katz created TheraBreath Healthy Gums Oral Rinse for his patients who suffered from gum health issues. Formulated with ingredients demonstrated to support and maintain healthy gums, this rinse has been shown to eliminate germs associated with gum disease. The proprietary blend of antibacterial agents goes to work quickly to help keep your gums looking and feeling their best.

**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 24 HOURS gingivitis protection, use every day and rinse twice daily after brushing and flossing. For best results, use as part of a twice daily regimen with TheraBreath Toothpaste.

Keep out of the reach of children. If spilled on fabric, washout immediately. This product was tested 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 a registered trademark of and manufactured for Dr. Harold Katz, LLC  
5902 Willoughby Av., L.A., CA, USA 90008  
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PHONE: 1-800-973-7374 WEB: THERABREATH.COM

16 fl. oz.  
473 mL



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**ORAL RINSE**



72551-247-05

72551-247-01

ANTINGIVITIS/ ANTIPLAQUE MOUTHRINSE

Made just for you by THERABREATH

SAVE!  
VALUE  
SIZE

PROFESSIONAL FORMULA  
**TheraBreath**<sup>®</sup>  
PERIODONTIST FORMULATED  
**HEALTHY GUMS**  
**ORAL RINSE**

FIGHTS GINGIVITIS FOR **24 HOURS**\*  
PROTECTS FROM PLAQUE & TARTAR • FRESHENS BREATH  
Reduces Occurrence of Gum Disease & Bleeding Gums  
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*Dr. Harold Katz*

**CLEAN MINT**

33.8 fl. oz.  
1 liter

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**Dr. Harold Katz**  
Dentist/ Bacteriologist

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This rinse may cause temporary staining to the surface of the teeth. This is not harmful, and adequate brushing may prevent its occurrence.

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PHONE: 1-800-973-7374 WEB: THERABREATH.COM



**Drug Facts**

**Active Ingredient** Polychlorine Chlorine 0.05% **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**  
• Gargling, 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 measuring spoons) 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.

**Other information**  
This rinse is not intended to replace brushing or flossing.

**Inactive ingredients:** Water, Glycerin, Poloxamer 407, Flavor, Sucralose



**ORAL RINSE**

SIZE: 5 5/16" x 10 1/4" RCR



72551-247-04

**ANTIGINGIVITIS/ ANTIPLAQUE MOUTHRINSE** Made just for you by THERABREATH

**POTENT CPC FORMULA**

**TheraBreath**  
PERIODONTIST FORMULATED  
**HEALTHY GUMS ORAL RINSE**

**FIGHTS GINGIVITIS FOR 24 HOURS\***  
PROTECTS FROM PLAQUE & TARTAR • FRESHENS BREATH  
Reduces Occurrence of Gum Disease & Bleeding Gums  
No Alcohol, No Artificial Flavors or Colors

*Dr. Harold Katz*

**CLEAN MINT**

**Drug Facts**

Active Ingredient	Purpose
Cetylpyridinium Chloride 0.05%	Antiplaque/Anti-tartar

**Uses**  
Helps prevent gingivitis, an early form of gum disease and bleeding gums which control plaque that leads to gingivitis and bleeding gums.

**Warnings**  
**Stop use and ask a dentist if:**  
• Gums bleed, bleed, or inflame persistently for more than 2 weeks.  
• You have painful or swollen gums, see your dentist, have teeth or crowns loosening, or teeth falling out.  
• You have a sore or swelling in your mouth.  
**Keep out of reach of children under 5 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: Rinse with 30 milliliters (1 ounce) of rinse between each brushing 2 to 4 times per day for 30 seconds and then spit out. Do not swallow the rinse.  
Children 6 years to under 12 years: Rinse once per day.  
Children under 6 years: Do not use.

**Other information**  
This rinse is not intended to replace brushing or flossing.  
**Inactive ingredients:** Water, Glycerin, Poloxamer 187, Flavors, Saccharin.

**3 fl. oz. / 88.7 mL**

**ORAL RINSE**

1-888-873-7374 / THERABREATH.COM



# THERABREATH HEALTHY GUMS ORAL RINSE

cetylpyridinium chloride rinse

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72551-247
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CETYLPYRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7J10JV3)	CETYLPYRIDINIUM CHLORIDE	0.0005 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>POLOXAMER 407</b> (UNII: TUF21VW3M2)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

## Product Characteristics

<b>Color</b>	white (Clear)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Clean Mint)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72551-247-01	473 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2020	
2	NDC:72551-247-04	33.8 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2020	
3	NDC:72551-247-05	88.7 g in 1 POUCH; Type 0: Not a Combination Product	12/01/2020	
4	NDC:72551-247-06	958.21 g in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2020	
5	NDC:72551-247-07	283.5 g in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2020	
6	NDC:72551-247-08	85.05 g in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2020	
7	NDC:72551-247-09	7.09 g in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2020	01/31/2022

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	12/01/2020	

**Labeler** - Dr. Harold Katz, LLC (965507767)

