

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.

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 be symptoms of periodontitis, a serious form of gum disease.

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 years	Do not use.

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

**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

ANTINGIVITIS/ ANTIPLAQUE MOUTHRINSE

Made just for you by **THERABREATH**

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 Wiltingbury Ave., LA, CA USA 90008
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PHONE: 1-800-973-7374 WEB: THERABREATH.COM



16 fl. oz.
473 mL

Drug Facts

Active Ingredient Chlorhexidine Chloride 0.05%	Purpose Antibacterial/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 of 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 swirl 20 milliliters (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.	
Other information This rinse is not intended to replace brushing or flossing. Inactive ingredients: Water, Glycerin, Poloxamer 407, Flavor, Sucralose	


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72551-247-05

72551-247-01

ANTINGINGIVITIS/ ANTIPLAQUE MOUTHRINSE

Made just for you by THERABREATH

SAVE!
VALUE
SIZE

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

33.8 fl. oz.
1 liter

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Dr. Harold Katz
Dentist/ Bacteriologist

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Keep out of the reach of children. If spilled on fabrics, wash out immediately. 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.

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



Drug Facts	
Active Ingredient	Purpose
Cetylpyridinium Chloride 0.05%	Antigingivitis/Antiplaque
Uses	
Helps prevent gingivitis, an early form of gum disease and bleeding gums. Wipes control plaque that leads to gingivitis and bleeding gums.	
Warnings	
Stop use and ask a dentist if: <ul style="list-style-type: none"> 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 measuring cups) 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	

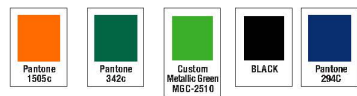


72551-247-04

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



72551-247-04



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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPIRIDINIUM - UNII:CUB7JIOJV3)	CETYLPIRIDINIUM CHLORIDE	0.0005 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLOXAMER 407 (UNII: TUF2IWW3M2)	
WATER (UNII: 059QF0KOOR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	white (Clear)	Score	
Shape		Size	
Flavor	MINT (Clean Mint)	Imprint Code	
Contains			

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)

