

THERABREATH FOR KIDS ANTI CAVITY ORAL RINSE- sodium fluoride 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 for Kids Anti Cavity Oral Rinse

Active Ingredient

Sodium Fluoride 0.05% (0.02%) w/v fluoride ion)

Purpose

Anticavity

Use

Aids in the prevention of dental cavities

Warnings

Keep Out Of Reach of Children.

Warnings

If more than used for rinsing is accidentally swallowed, get help or contact a Poison Control Center right away.

Directions

- Adults and children 6 years of age and older: Use once a day after brushing your teeth with a toothpaste. Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out. Do not

swallow the rinse.

- Do not eat or drink for 30 minutes after rinsing.
- Instruct children under 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.
- Children under 6 years of age: Consult a dentist or doctor.

Other information

Do not use if safety seal is broken or missing

Inactive Ingredients

Water, Glycerin, Sodium Benzoate, Flavor (Organic), Xylitol, Citric Acid, Sucralose, Sodium Citrate

TheraBreath Kids Anti Cavity Oral Rinse

ANTICAVITY / FLUORIDE ORAL RINSE

Made just for you by THERABREATH



TheraBreath
for KIDS!

DENTIST FORMULATED
ANTI CAVITY
ORAL RINSE

Safe for Kids
Keeps Teeth Healthy and Breath Fresh
No Artificial Flavors or Colors

Certified ORGANIC GRAPE FLAVOR
GORILLA GRAPE

Here's Our Story:

Dr. Harold Katz created the TheraBreath formula in 1993 for his own family. That's why our products contain no artificial flavors or colors, no alcohols or detergents, and are vegan and gluten free. Outside of water, there is nothing you put in your mouth more regularly than your oral care products. That's why healthy ingredients matter.

Our Guarantee To You:

Every TheraBreath product is guaranteed to be the most effective oral care product you have ever used. If you are not completely satisfied, please contact us for refund instructions.

Important:
Read directions for proper use.

16 fl. oz.
473 mL

Drug Facts

Active Ingredients	Purpose
Sodium Fluoride 0.05% (0.012 wt% fluoride ion)	Anticavity

Use:
Rinse in the prevention of dental cavities.

Warnings:
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 6 years of age and older: Use once a day after brushing your teeth with a toothpaste. Vigorously swish 10 milliliters of rinse behind your teeth for 1 minute and then spit it out. Do not swallow the rinse.
• Do not eat or drink for 30 minutes after rinsing.
• In strict children under 10 years of age in good rinsing habits the minimum swallowing. Supervise children as necessary until capable of using without supervision.
Children under 6 years of age: Can suit a dentist or doctor.

Other Information:
Do not use if safety seal is broken or missing.

Inactive Ingredients: Water, Glycerin, Sodium Benzoate, Flavor (Organic), Xylitol, Citric Acid, Sucralose, Sodium Citrate.

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Manufactured for Dr. Harold Katz, LLC.
5802 Willowoughby Av., L.A., CA USA 90008
PHONE: 1-800-973-7274
WEB: THERABREATH.COM

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Inactive Ingredients: Water, Glycerin, Sodium Benzoate, Flavor (Organic), Xylitol, Citric Acid, Sucralose, Sodium Citrate.

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IMPORTANT:
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ORAL RINSE

THERABREATH FOR KIDS ANTI CAVITY ORAL RINSE

sodium fluoride rinse

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:72551-254

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.0005 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GLYCERIN (UNII: PDC6A3C0OX)	
GRAPE (UNII: 6X543N684K)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE (Grape (Organic))	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72551-254-01	473 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/01/2018	

Labeler - Dr. Harold Katz, LLC (965507767)