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.

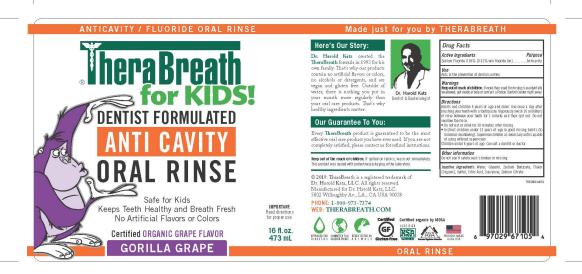
Other information

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





THERABREATH FOR KIDS ANTI CAVITY ORAL RINSE sodium fluoride rinse Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:72551-254

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) 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			

Packagi	Packaging				
# Item (Code	Package Description		Marketing Start Date	Marketing End Date
1 NDC:725 254-01		1 BOTTLE, PLASTIC; Type 0: Not a tion Product	a	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)

Revised: 2/2022 Dr. Harold Katz, LLC