

**TheraBreath Fresh Breath- sodium fluoride paste, dentifrice**  
**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 Fresh Breath**

***Active Ingredients***

Sodium Fluoride 0.24%  
(0.14% W/V fluoride ion)

***Purpose***

Anticavity Fluoride Dentrifrice

***Uses***

Aids in the prevention of dental cavities

***Directions***

Adults & Children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor.

***Warnings***

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

***Warnings***

**Keep out of reach of children under 6 years of age.**

***Other information***

- If spilled on fabrics, wash out immediately.
- This product was sealed with protective packaging at the laboratory.
- If seal is missing, do not use.

***Inactive Ingredients***

Sorbitol, Water (Aqua), Hydrated Silica, Glycerin (from vegetable sources), Xylitol, Natural Flavor, Cellulose Gum, Tetrapotassium Pyrophosphate, Tetrasodium Pyrophosphate, Sodium Benzoate, Aloe Barbadensis Leaf Juice, Citric Acid, Sodium Chlorite (OXYD-8™), Ammonium Glycyrrhizate, Ascorbic Acid (Vitamin C), Mentha Arvensis (Cornmint) Leaf Oil, Mentha Viridis (Spearmint) Leaf Oil, Natural Fragrance (Parfum)

## **TheraBreath Fresh Breath**

**ANTICAVITY TOOTH PASTE** Keep Cap Closed Tightly After Each Use

**NEW LONGER LASTING FORMULA**

PROFESSIONAL FORMULA

# TheraBreath®

DENTIST FORMULATED

## FRESH BREATH TOOTH PASTE

FRESHENS BREATH FOR **24 HOURS\***

AntiCavity / AntiTartar  
With Soothing Aloe Vera

*Dr. Harold Katz*

net wt. 4 oz. • 113.5 g

**MILD MINT**

**Drug Facts**

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**Uses**  
Aids in the prevention of dental cavities

**Warnings**  
**Keep out of reach of children under 6 years of age.** If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**  
Adults & Children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and flossing habits to minimize swallowing. Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor.

**Other information**

- If spilled on fabric, wash out immediately.
- This product was sealed with protective packaging at the laboratory.
- If seal is missing, do not use.

**Inactive ingredients**  
Sorbitol, Water (Aqua), Hydrated Silica, Glycerin (from vegetable sources), Xylitol, Natural Flavor, Cellulose Gum, Tetrapotassium Pyrophosphate, Tetrasodium Pyrophosphate, Sodium Benzoate, Aloe Barbadosensis Leaf Juice, Citric Acid, Sodium Chloride (XFD-8™), Ammonium Glycyrhizate, Ascorbic Acid (Vitamin C), Mentha Arvensis (Common Mint) Leaf Oil, Mentha Viridis (Spearmint) Leaf Oil, Natural Fragrance (Parfum)

**\*For 24 HR fresh breath, brush with TheraBreath Toothpaste twice daily.**

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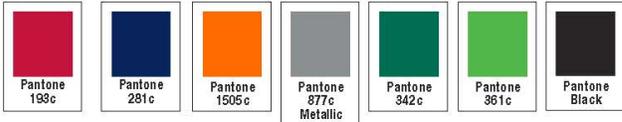
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ROSHIER

AVA  
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in the USA

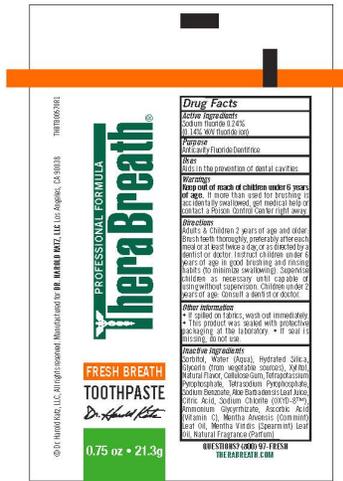
**THEARBREATH.COM**

Please Remember to Recycle



**Outer Packaging Box**





## THERABREATH FRESH BREATH

sodium fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72551-250
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.0024 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>SPEARMINT</b> (UNII: J7I2T6IV1N)	
<b>MENTHA ARVENSIS FLOWER OIL</b> (UNII: Q129Z1W6Y2)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)	
<b>SODIUM CHLORITE</b> (UNII: G538EBV4VF)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	

<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>POTASSIUM PYROPHOSPHATE</b> (UNII: B9W4019H5G)	
<b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72551-250-01	1 in 1 PACKAGE	10/04/2018	
1		113.5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:72551-250-02	21.3 g in 1 TUBE; Type 0: Not a Combination Product	10/04/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/04/2018	

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

Revised: 2/2022

Dr. Harold Katz, LLC