# THERABREATH PLUS 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 Plus Fresh Breath

### **Active Ingredients**

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

## **Purpose**

Anticavity Fluoride Dentrifice

#### Uses

Aids in the prevention of dental cavities

## Warnings

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

# Warnings

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 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.

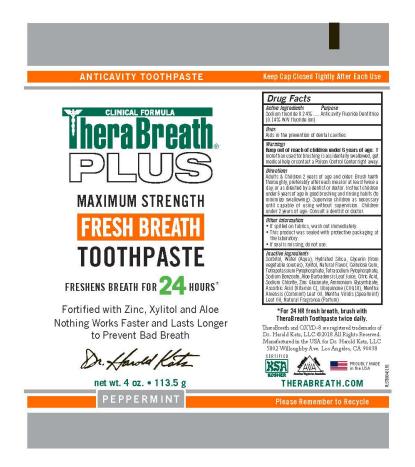
#### Other information

- 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, Zinc Gluconate, Ammonium Glycyrrhizate, Ascorbic Acid (Vitamin C), Ubiquinone (COQ10), Mentha Arvensis (Cornmint) Leaf Oil, Mentha Viridis (Spearmint) Leaf Oil, Natural Fragrance (Parfum)

#### TheraBreath Fresh Breath Label

















# THERABREATH PLUS FRESH BREATH

sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72551-251
Route of Administration	DENTAL		

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

Inactive Ingredients		
Ingredient Name	Strength	
UBIDECARENONE (UNII: EJ27X76M46)		
SPEARMINT (UNII: J7I2T6IV1N)		
MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N)		
ASCORBIC ACID (UNII: PQ6CK8PD0R)		
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)		
SODIUM CHLORITE (UNII: G538EBV4VF)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)		
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)		
XYLITOL (UNII: VCQ006KQ1E)		
GLYCERIN (UNII: PDC6A3C0OX)		
HYDRATED SILICA (UNII: Y6O7T4G8P9)		
WATER (UNII: 059QF0KO0R)		

SORBITOL (UNII: 506T60A25R)	
ZINC GLUCONATE (LINII: LIGNENISSO17)	

Product Characteristics			
Color	white (Clear)	Score	
Shape		Size	
Flavor	MINT (Mild Mint)	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:72551-251- 01	1 in 1 PACKAGE	10/04/2018		
1		113.5 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:72551-251- 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